

Exhibit 75

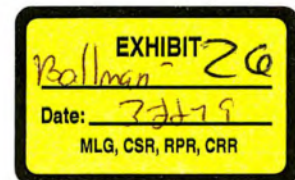
**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY
LITIGATION**

MDL NO. 16-2738 (FLW) (LHG)

THIS DOCUMENT RELATES TO ALL CASES

**EXPERT REPORT OF CHRISTIAN MERLO, MD, MPH
FOR GENERAL CAUSATION *DAUBERT* HEARING**



Date: February 25, 2019

Christian A. Merlo

Christian Merlo, M.D., M.P.H.

Author	OR (95% CI)	OR (95% CI)	Statistical significance
Hospital-based case-control studies			
Hartge et al. (1983)	0.70	0.04-1.10	No
Whittemore et al. (1988)	1.45	0.81-2.60	No
Booth et al. (1989)	1.30	0.80-1.90	No
Rosenblatt et al. (1992)	1.70	0.70-3.90	No
Tzonou et al. (1993)	1.05	0.28-3.98	No
Hartge and Stewart (1994)	0.30 (5-9 years of talc exposure) 0.50 (10+ years)	0.10-1.40 0.20-1.50	No
Wong et al. (1999)	1.13	0.88-1.44	No
Population-based case-control studies			
Cramer et al. (1982)	1.92	1.27-2.89	Weak
Harlow and Weiss. (1989)	1.10	0.70-2.10	No
Harlow et al. (1992)	1.50	1.00-2.10	Weak
Chen et al. (1992)	3.90	0.90-10.5	No
Cramer and Xu (1995)	1.60	1.20-2.10	Weak
Purdie et al. (1995)	1.27	1.04-1.54	Weak
Green et al. (1997)	1.30	1.10-1.60	Weak
Shushan et al. (1996)	1.97	1.06-3.66	Weak
Chang and Risch (1997)	1.42	1.08-1.86	Weak
Cook et al. (1997)	1.60	0.90-2.80	No
Godard et al. (1998)	2.49	0.94-6.58	No
Cramer et al. (1999)	1.60	1.18-2.15	Weak
Ness et al. (2000)	1.50	1.10-2.00	Weak
Mills et al. (2004)	1.37	1.02-1.85	Weak
Pike et al. (2004)	1.60	1.18-2.18	Weak
Jordan et al. (2007)	1.00	0.40-2.10	No
Gates et al. (2008)	1.36	1.14-1.63	Weak
Merritt et al. (2008)	1.17	1.01-1.36	Weak
Moorman et al. (2009)	Afr. Am.: 1.19 Caucasian: 1.04	Afr. Am.: 0.68-2.09 Caucasian: 0.82-1.33	No
Wu et al. (2009)	1.53	1.13-2.09	Weak
Rosenblatt. (2011)	1.27	0.97-1.66	No
Kurta et al. (2012)	1.40	1.16-1.69	Weak
Wu et al. (2015)	1.46	1.27-1.69	Weak
Schildkraut et al. (2016)	1.44	1.11-1.86	Weak
Pooled case-control studies			
Terry et al. (2013)	1.24	1.15-1.33	Weak

Author	Odds Ratio/Relative Risk/Hazard Ratio	95% CI	Statistically Significant Association?
Cramer et al. (2016)	1.33	1.16-1.52	Weak
Cohort studies			
Gertig et al. (2000)	1.09	0.86-1.37	No
Gates et al. (2010)	1.06	0.89-1.28	No
Houghton et al. (2014)	1.12	0.92-1.36	No
X Gonzalez et al. (2016)	0.73	0.44-1.20	No

Exhibit 76

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P1.0215



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Hospital-based case-control studies			
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Gonzalez et al. (2016)	0.73	0.44-1.20	No

Exhibit 77

Applying Bradford Hill's Criteria for Causation to Neuropsychiatry: Challenges and Opportunities

Robert van Reekum, M.D., F.R.C.P.C.
David L. Streiner, Ph.D., C.Psych.
David K. Conn, M.B., F.R.C.P.C.

scientific implications. Sir Austin Bradford Hill

tion, consistency, specificity, temporal sequence,

E
tant research activity because it influences the de-
livery of good medical care. A finding of causation in-
fluences decisions related to prognosis, diagnosis, and
treatment, and it may have medical-legal ramifications.
E

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) . F

(J 2001; 13:318 325) C
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7, 2000; 8, 2000; 25, 2000.
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G , C ; D
, D . , C , A , B
C G C , 3560 B , 6A
2E1, C C 2001 A , I .

C A B,

A B

possibility that some unidentified third factor, C, is in

1. G

CRITERIA FOR CAUSATION

possible on potential determinants identified from the

ables. Direct comparisons of the identified significant interest, is then required in further research to confirm the role of the preliminarily identified causative agents.

Dated for specific neuropsychiatric disorders remain B

often very difficult, as the causative agent may produce

B A (AD). ? C B

I 4

2. Consistency of the Evidence

I A B, I (. , ,) available, and they should all lead to consistent findings A B. I findings are inconsistent, then it is very important to be at the heart of the discrepant findings. If no reason- C findings is a necessary criterion for causation in neuro- findings is available (i.e., an argument of causation will F).

3. Specificity

C in neuropsychiatry; that is, if specificity can be demon- if specificity is lacking, then this in no way detracts from

4. Temporal Sequence

C A B, A B. B difficult to establish in neuropsychiatry. A ()

5. Biological Gradient

may be difficult to establish, in neuropsychiatric con-

variable influencing the impact of the lesion on the func-

reflect the degree of cortical involvement brought about

of the insult, but both clearly may be influenced by non-

establishing a finding of new-onset cases or some new-

we know when the causative agent first appeared, and

AD⁵

AD,⁶

AD.

changes of AD first produce the late-onset depression,

AD.

to be satisfied in the future. At present, however, given

gument of causation, it is often very difficult to be cer-

CRITERIA FOR CAUSATION

cal gradient should be considered supportive of an argument for causation in neuropsychiatry, but the absence of a biological gradient may not preclude the determination of a causative relationship.

6. Biologic Rationale

There is a greater likelihood of a causative relationship being present if it makes biological sense that A causes B. Whether or not it makes sense that a putative causative agent causes the outcome of interest is important to us as humans because we need to fit research findings into our understanding of our world and ourselves. But how we understand our world and ourselves is clearly a function of the state of our belief systems at present, and “reality” changes as new belief systems evolve. Although it once made sense that body fluids such as bile were determinants of Behavior, this does not make sense today.

Many of our perceptions about determinants of Behavior are influenced today by post-psychoanalytic thought and by cultural expectations (such as the expectation that we be “in control” of our emotions). Modern neuropsychiatry is once again shifting the focus back to biological processes as determinants of Behavior, but our judgment as to whether arguments of causation for changes in brain function affecting Behavior are valid will continue to be influenced by our preconceived notions of the world and ourselves. Interestingly, it seems that we are much more likely to accept the role of the brain in determining changes in cognitive function than we are to accept its role in determining changes in mood and behavior. It may be that such possibilities threaten us, in the sense of undermining our need for self-control. Whatever our reasons for not considering certain arguments of causation to be biologically plausible, we need to constantly remind ourselves that just because the argument doesn’t make sense to us does not necessarily mean that it isn’t true. A biologic rationale is necessary for establishing an argument for causation, but it may not be accepted by everyone in the here and now.

7. Coherence

This is similar to the biologic rationale criterion. It stipulates that there is a greater likelihood that A causes B if this postulated causal relationship is consistent with what is already known about the disease or disorder. Clearly the relevance of this criterion will depend to a large extent on the amount of knowledge that we have at the moment. As with the biologic rationale criterion, if this criterion is met, then it is supportive of an argument of causation; if not, then we may simply not yet

know enough, or we may need to revisit that which we think we know.

8. Experimental Evidence

Experimental evidence is the most compelling evidence of causation. If it can be shown that experimentally (ideally randomly) inducing the causative agent consistently produces the outcome, at greater rates than in a nonexposed control sample, this is clear and compelling evidence of causation. However, it is obvious that such evidence will be rare in neuropsychiatry, as it is grossly unethical to induce most forms of brain dysfunction experimentally in humans. Transient alterations in brain function, such as with apomorphine or transcranial magnetic stimulation, are sometimes the exception to this ethical concern and may yield important results in the future. Experimental approaches are often applied to nonhuman species, but this practice is also increasingly considered to raise ethical concerns. Further, the nonhuman brain has important differences in brain structure and function that may mislead researchers investigating causation in humans.

Some experimental evidence in humans, however, may be forthcoming from results of treatment studies. Indeed, the dopamine hypothesis of schizophrenia was born from observations of response to treatment with dopamine-active agents such as chlorpromazine. The problem with this type of thinking is that conditions may respond to a treatment that does not necessarily address the causative agent. For example, few believe that headaches are caused by an absence of aspirin, despite the fact that headaches may decrease with aspirin. While there is no “hypoaspirinemia” theory of headaches, this type of experimental evidence may provide important leads into causative relationships. The role of prostaglandins in the formation of pain responses is an example that flows from the observation that aspirin relieves pain.

These limitations on the use of experimental evidence limit the utility of this criterion for causation in neuropsychiatry, rendering it a helpful but not a necessary criterion at present.

9. Analogous Evidence

This approach takes the form of thinking that if some condition similar to A causes an outcome similar to B, then this is evidence that A causes B. While analogous evidence is helpful, there are clearly major limitations to this approach in neuropsychiatry. Although different types of insults to the brain may share certain features, they also usually have important differences as well. Furthermore, the nature of the lesion may influence the expression of the outcome of interest in important ways.

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CRITERIA FOR CAUSATION

... F ... BI ...

SUMMARY

2. Can TBI Cause Psychiatric Disorders?

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first time after TBI. There was little evidence of a BI of the findings, a biologic rationale, and the appropriate

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tified, such as presence of pre-TBI psychiatric disorders ...

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... ment of causation. How is it that we finally become con-

A B?

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2. D , G , B H: D E . 2000; 12:316 327 ? J
3. D C E B : H 12. , C BK, : D 1998; 79:90 103
4. C AJ 1981; 124:985 990 , I : . 13. D , I, K C, : 1999; 156:374
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6. A E E J 1996; 334:752 758 E4 15. JE, K , B I 1998; 12:177 190
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8. ? J C 1998; 10:103 107 17. F J , K J, J , : .
9. 217 . A J 1992; 26:208 18. A J 1995; 152:1493 1499
10. H A: D . B 1988; 111:375 387 19. F J , E, F A , : D -
- C 1996; 8:453 457 . J . A J 1992; 149:918 923

Exhibit 78

TALC AND CARCINOMA OF THE OVARY AND CERVIX

BY

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Velindre Memorial Centre for Cancer Research

A. C. TURNBULL, *Professor of Obstetrics and Gynaecology*
Welsh National School of Medicine

AND

K. GRIFFITHS, *Director*

Tenovus Institute for Cancer Research, Welsh National School of Medicine, Cardiff

Summary

An extraction-replication technique was used to examine tissue from patients with ovarian and cervical tumours. In both conditions talc particles were found deeply embedded within the tumour tissue. The close association of talc to the asbestos group of minerals is of interest.

The development in this laboratory of an extraction-replication technique (Henderson, 1969) for the study of foreign particles within tissues has allowed the *in situ* identification of crocidolite asbestos within the tissue of various mesotheliomas (Henderson *et al.*, 1969) removed from patients who had been concerned with the manipulation of asbestos in industry. This technique has now been applied to the study of tissue from ovarian and cervical carcinoma.

MATERIALS AND METHODS

Tissue

The tissue studied was obtained from patients with cancer of either the ovary or the cervix, and was first prepared as paraffin sections for normal routine histological examination but was unstained. Sections were then stained for histological assessment in the usual manner, and adjacent unstained tissue prepared for electron microscopy.

Replication Technique

The extraction-replication procedure has been described (Henderson, 1969). Sections of tissue were immersed in xylene and in ethanol, and the dehydrated tissue was then embedded by

immersing the section on to the surface of a thin sheet of acetone-softened cellulose acetate, mounted on a glass slide, and left to harden. On removing the slide, the embedded tissue was left in the cellulose acetate. The tissue was then outlined with thin strips of Scotch tape to form a shallow well, and a 10 per cent (v/v) polyvinyl alcohol (PVA) solution applied. When the PVA had hardened it was stripped from the section providing a replica of the tissue surface. Foreign particles associated with the tissue are often removed with the PVA during this stripping process.

A complete sequential examination through the embedded tissue is possible by taking successive strippings. These surface replicas were then preshadowed with platinum, a carbon film deposited for strength, and the PVA removed by floating the replica in a hot water bath. Replicas were mounted on electron microscope grids for examination, using the AEI-6B microscope.

RESULTS

No asbestos particles were found in any of the tissue studied. Particles of talc were identified in approximately 75 per cent (10 of 13) of the

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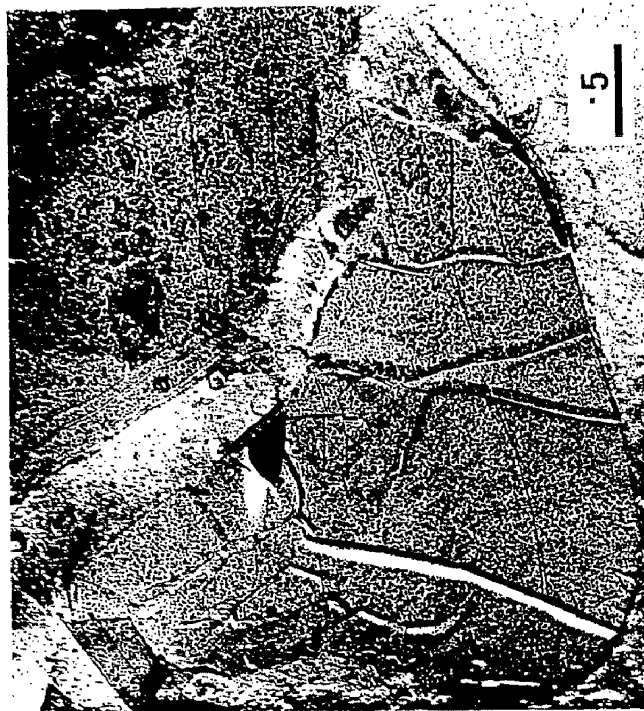


FIG. 1
Typical decoration pattern on a particle of natural talc. Numerous crystal lattice planes are shown (a). ($\times 30\,000$). Scale refers to $1.0\,\mu$.



FIG. 2
Commercial talc preparations illustrating the decoration pattern. ($\times 40\,000$).

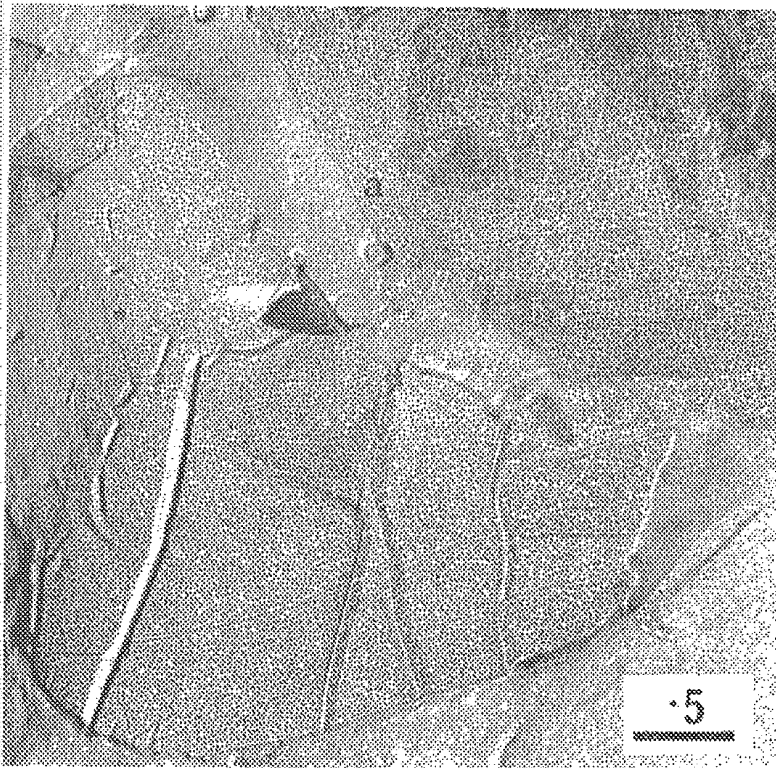


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Scale refers to 1.0μ .

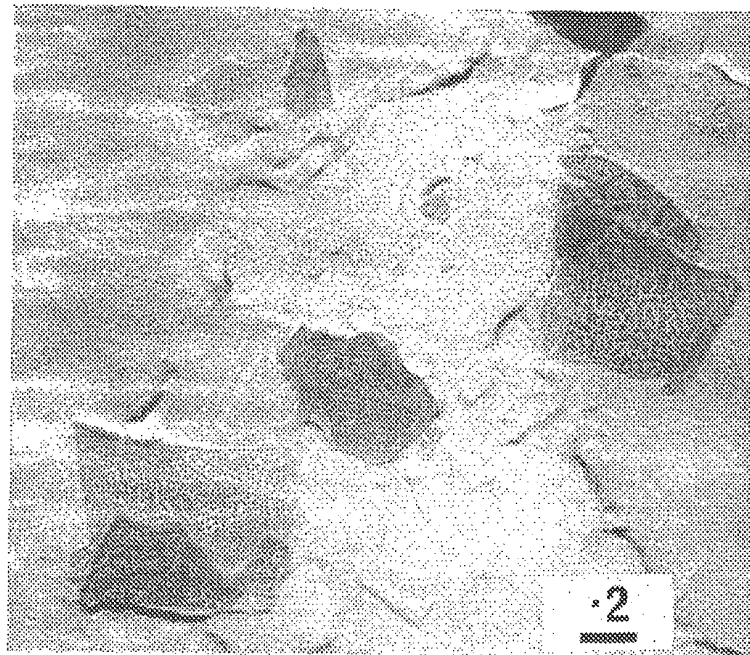


FIG. 2
Commercial talc preparations illustrating the decoration pattern. ($\times 40,000$)

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FIG. 3

Micrograph of tissue from a serous papillary cystadenocarcinoma of the ovary removed from a 27-year-old female. No previous abdominal operations had been carried out. The decoration pattern and lattice planes are shown. ($\times 30,000$.)

ovarian tumours. Using the replication technique identification of talc is possible because of the characteristic "decoration pattern" induced by the evaporation of platinum *in vacuo* on the crystal surface. Figure 1 shows this pattern on a particle of natural talc and the distinctive lattice planes of the crystals. Anthophyllite asbestos, which is known to be converted naturally to talc, is the only crystalline material which is at present indistinguishable from talc by using the replication technique. The decoration pattern on material from a commercial talc preparation is also demonstrated in Figure 2.

Material found within the ovarian tumours

and identified as talc is illustrated in Figure 3. The talc particles were found deep within the tumour tissue. Some were as small as 1000\AA in size but they were generally within a range from 1000\AA to $2\text{ }\mu$.

Talc particles were also found embedded within tumours of the cervix. Figure 4 shows one such particle embedded in a capillary wall within the tumour, and Figure 5 illustrates the decoration pattern of the particle at a higher magnification. Crystals as large as $5\text{ }\mu$ were found in tissue from the cervical tumours and were generally larger than those seen in the ovarian tumours. Talc crystals were found in



FIG. 4

Micrograph of tissue from a squamous-cell carcinoma of the cervix from a 62-year-old female. C—capillary, R—red cell. The particle of talc can be seen in the wall of the capillary. ($\times 3500$.)



FIG. 5

A higher magnification of the talc particles outlined in Fig. 4. The typical decoration pattern is shown. ($\times 40,000$.)

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FIG. 3

Micrograph of tissue from a serous papillary cystadenocarcinoma of the ovary removed from a 27-year-old female. No previous abdominal operations had been carried out. The decoration pattern and lattice planes are shown. ($\times 30\,000$.)

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TALC AND CARCINOMA OF THE OVARY AND CERVIX 269

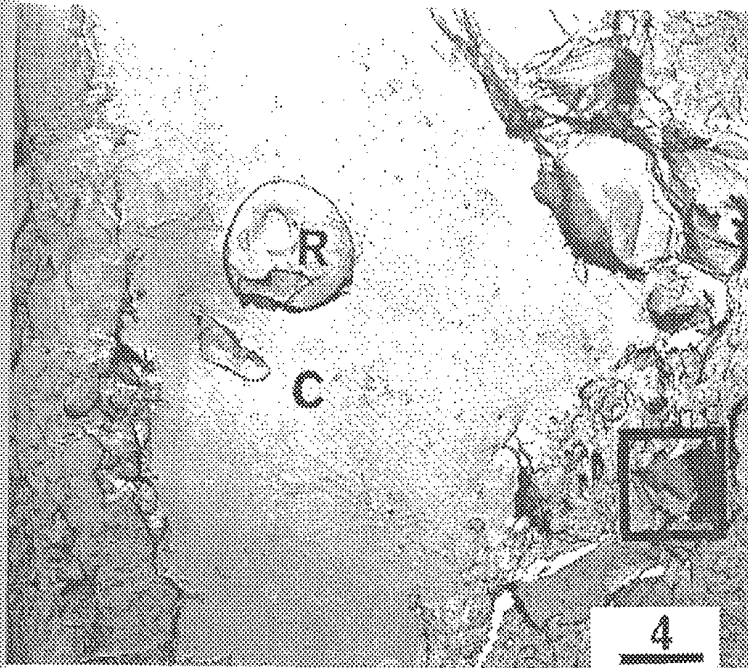


FIG. 4

Micrograph of tissue from a squamous-cell carcinoma of the cervix from a 62-year-old female. C—capillary, R—red cell. The particle of talc can be seen in the wall of the capillary. ($\times 3500$.)

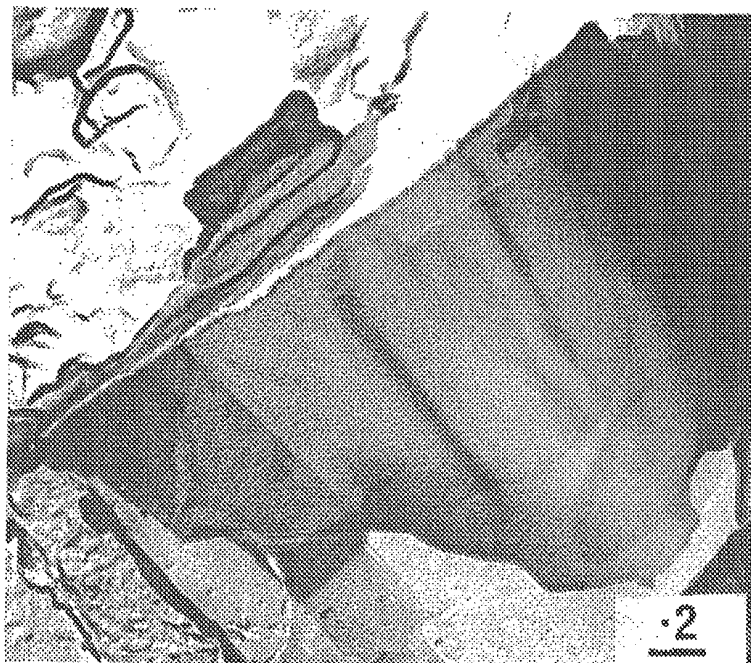


FIG. 5

A higher magnification of the talc particles outlined in Fig. 4. The typical decoration pattern is shown. ($\times 40\,000$.)

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approximately 50 per cent of the cervical tumours examined (12 of 21) but it must be realized that these particles are extremely minute, often with the dimensions of viruses, and only small regions of the tumour tissue could be studied. Approximately ten replication "strippings" for electron-microscope examination are usually taken from each thin section of the tissue. Figure 6 illustrates the use of the technique in the examination of pneumoconiotic lung tissue from a patient whose industrial history indicated long exposure to Norwegian talc.

Many particles of talc were found concentrated in the deeper layers of a primary carcinoma of the endometrium (Fig. 7) whereas extensive studies of a secondary tumour in the ovary in the same patient did not show the presence of talc. Application of the technique to "normal" ovarian tissue removed from patients with breast cancer has also shown talc particles in 5 of 12 such tissues studied. Extensive study at high magnification with the electron microscope is, however, required for evaluation of a replica and particles could easily be missed.

The application of electron-microscope microanalysis (EMMA-AEI, Harlow, England) to the particles extracted by the replication technique has provided preliminary evidence that the crystals contain magnesium and silicon, talc being a magnesium silicate.

DISCUSSION

The possibility that the increasing incidence of carcinoma in western society may be related to a corresponding increase in the use of asbestos (Graham and Graham, 1967) is of interest, especially with regard to pleural and peritoneal mesotheliomas in workers exposed to crocidolite asbestos in industry (Wagner *et al.*, 1960; Elwood and Cochrane, 1964). There have been a number of reports about the relationship between asbestos and carcinogenesis (Smith *et al.*, 1965; Jacob and Anspach, 1965). However, the identification of asbestos fibres within tissue is extremely difficult. Fine particles embedded within tumour tissue are usually beyond the limits of resolution of the optical microscope, and tissue incineration, followed by electron microscopy of the isolated particles, may be unreliable if chemical changes are

induced by the procedure. Using normal light microscopy, identification of asbestos particles is based on the presence of characteristic ferritin bodies on some of the fibres, although these cannot easily be distinguished from similar bodies around elastin fibres (Henderson *et al.*, 1970). This procedure may not, however, be as unreliable as the use of polarized light for the demonstration of brightly illuminated "birefringent crystals of asbestos".

The replication technique (Henderson, 1969) failed to show asbestos fibres in the ovarian neoplasms studied. On the other hand, there was good evidence for the presence of talc, often indistinguishable from anthophyllite asbestos, within the ovarian tissue. (Anthophyllite is converted naturally to talc.) The talc particles were found localized deep within tumour tissues, and not universally dispersed throughout the tumour. The talc particles in the ovary were generally much smaller than those found in the tissue from the tumours of the cervix.

The relationship between asbestos and mesotheliomas appears well established, and the replication technique has provided unequivocal evidence for the presence of fibres within such tumours. This technique has also produced evidence for the presence of talc in tissue from pneumoconiotic lungs of a patient with an industrial history of exposure to Norwegian talc (Henderson *et al.*, 1970). The presence of mica, kaolin and asbestos fibres were also identified in tissue from these pneumoconiotic lung tissue.

Although it is impossible to incriminate talc as a primary cause of carcinomatous changes within either the cervix or the ovary on the preliminary observations described here, the possibility that talc may be related to other predisposing factors should not be disregarded and further investigations are obviously required.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the generous financial support of the Tenovus Organization. They also thank Dr. J. W. Dobbie, Department of Pathology, Royal Infirmary, Glasgow, for supplying a number of tissue sections, and also Mr. D. E. Evans, Department of Geology, National Museum of Wales, for the natural minerals required for reference purposes.



FIG. 6
Talc particles found in
tissue from a pneumo-
coniotic lung. ($\times 30\,000$.)



FIG. 7
Micrograph from the deepest part of an extensive papillary adenocarcinoma entirely replacing the endometrium in a 58-year-old woman, 8 years postmenopausal. Both ovaries were enlarged by hilar metastases, showing histological features similar to the primary endometrial lesion. Numerous talc particles were found in the primary endometrial carcinoma, but none in the metastatic ovarian tumours. ($\times 25\,000$.)



FIG. 6
Tail particles found in
tissue from a pneumo-
coniotic lung. ($\times 30,000$.)

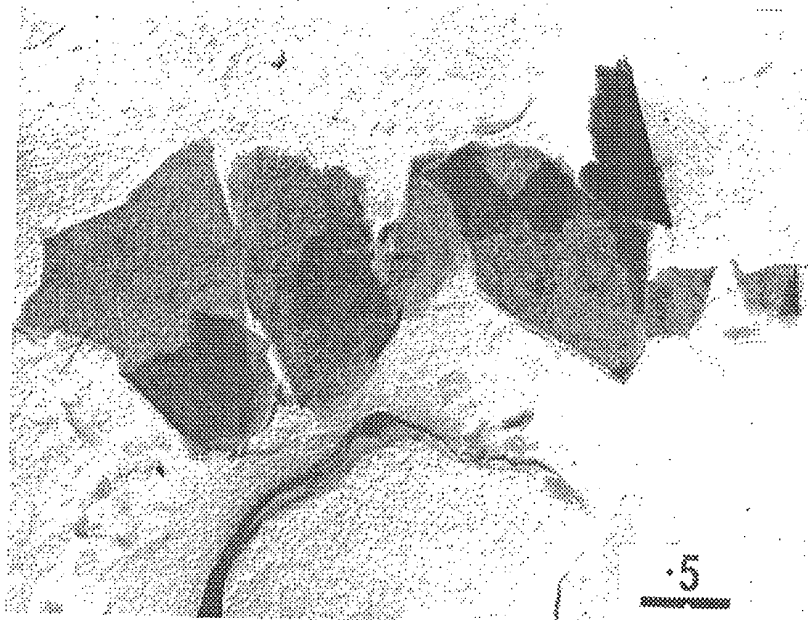


FIG. 7
Micrograph from the deepest part of an extensive papillary adenocarcinoma entirely replacing
the endometrium in a 58-year-old woman, 8 years postmenopausal. Both ovaries were
enlarged by hilar metastases, showing histological features similar to the primary endometrial
lesion. Numerous tail particles were found in the primary endometrial carcinoma, but none
in the metastatic ovarian tumours. ($\times 26,000$.)

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Exhibit 79

The relationship between perineal cosmetic talc usage and ovarian talc particle burden

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OBJECTIVE: Epidemiologic studies support the hypothesis of a dose-related risk of epithelial ovarian cancer with perineal talc exposure. Frequency and duration of talc usage has not been previously correlated with ovarian talc content.

STUDY DESIGN: Ovaries were studied from 24 women undergoing incidental oophorectomy who were interviewed regarding talc usage. Twelve subjects reported frequent perineal talc applications; the twelve controls reported no use. Ovarian tissue blocks were digested and analyzed by polarized light microscopy and analytic electron microscopy to identify and quantify talc.

RESULTS: Talc was identified in all 24 cases by either light or electron microscopy. Talc particle counts were completely unrelated to reported levels of perineal talc exposure.

CONCLUSIONS: The detection of talc in all ovaries demonstrates that it can reach the upper genital tract. Widespread exposure to talc during diapering may contribute to the ubiquitous presence of talc in ovarian tissue. (AM J OBSTET GYNECOL 1996;174:1507-10.)

Key words: Talc, ovary

Epidemiologic evidence suggests that perineal exposure to talc is associated with an increased risk of epithelial ovarian cancer in a dose-related fashion.^{1,5} Other epidemiologic studies have shown no increased risk of ovarian cancer associated with talc.^{6, 7} Studies show access of particulate matter into the female peritoneal cavity through the transvaginal route.⁸⁻¹⁰ A few reports have identified talc in ovarian tissue,^{11, 12} both benign and malignant, but these data were not correlated with an exposure history. Other potential genital tract exposures in a woman's life include surgical gloves,¹³ condoms, and diaphragms. Diapering with talc during infancy is another potential exposure. Epidemiologic studies have not linked these exposures to an increased risk of ovarian cancer.^{1, 2}

If transvaginal transport of perineally applied talc occurs, women with the heaviest exposures may show the largest talc particle burdens in their ovaries. Tissue digestion techniques are an accepted analytic adjunct in the identification and quantification of asbestos in the lungs of occupationally exposed individuals^{14, 15} and are useful in the identification and quantification of talc as well.

The goal of this pathoepidemiologic study was to correlate the history of perineal talc usage with the talc particle burden found in the ovaries.

Material and methods

In a case control study of benign ovarian neoplasms at Columbia Presbyterian Medical Center, women undergoing surgery from 1992 to 1993 were interviewed regarding various factors, including talc usage. Subjects were also questioned regarding possible occupational exposures to asbestos, and mothers were contacted regarding diapering history whenever feasible.

Subjects were categorized for talc exposures as follows. Women who reported no direct application of talc to the perineum or to underwear were considered unexposed. For women who reported talc application to underwear or the perineum, the total number of lifetime applications was estimated as the average frequency of use times the number of years of use. For instance, a woman who reported perineal talc application twice per day for 10 years was considered to have 7240 applications. To simplify the classification of exposed and unexposed women, subjects who reported tubal ligation, diaphragm use, or feminine hygiene spray use were excluded from this analysis.

Interviewed subjects from the parent case control study who had a normal contralateral ovary in the surgical specimen were eligible for this substudy. Sections of normal ovary from the 12 women who reported the largest number of perineal talc applications were analyzed. For each of these subjects the unexposed woman closest in age was selected as a control. In addition, the ovaries of two stillborn fetuses were analyzed as negative controls.

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Table I. Talc particle counts in women who reported perineal cosmetic talc usage

Subject No.	age (yr)	Lifetime talc applications*	EM talc particle counts†	Polarized light microscopic counts†	Asbestos detected	Talc use with diapering
1	49	4,784	1,600,288	96	No	Yes
2	49	5,475	0	54	No	Unknown
3	57	6,552	0	100	Yes	No
4	31	8,144	0	114	No	Unknown
5	43	10,556	0	464	Yes	Unknown
6	45	11,284	151,300	300	No	Yes
7	50	11,648	236,406	345	No	Yes
8	57	15,600	0	75	No	Yes
9	66	18,980	0	250	Yes	Yes
10	47	21,840	1,576,000	111	No	Unknown
11	44	23,660	0	348	No	Yes
12	44	39,312	7,565,000	26	Yes	Unknown

EM, Electron microscopy.

*Frequency of use × Years of use.

†Per gram wet tissue weight.

Ovarian tissue in blocks was deparaffinized, rehydrated, blotted dry, and weighed. Digestion with 5% potassium hydroxide was performed at 70° C for 2 to 4 hours. After complete digestion, the tissue was centrifuged at 12,000 revolutions/min for 20 minutes. The potassium hydroxide was removed, leaving a pellet to which approximately 20 ml of distilled water was added. The pellet was resuspended by use of a microultrasonic cell disrupter at 50 W for 5 seconds. Centrifugation, distilled water wash, and microultrasonic cell disrupter were repeated three times. The distilled water was removed, and the pellet was resuspended in 5 to 10 ml of distilled water. Drops of 10 μ l of the final suspension were placed on nickel formvar and carbon-coated locator grids and air-dried. Transmission electron microscopy to identify particles and their size was performed. The identity of the particles was determined by energy-dispersive spectroscopy and confirmed by electron diffraction. Grids were viewed at both 10,000 and 19,000 diameters. All talc particles observed were counted. Cytospin slides for polarized light microscopy were prepared from the same final suspension as the electron microscopy grids. Polarized light microscopy counted larger talc particles (limits of detection approximately 1 μ m), whereas electron microscopy detected smaller ones (limits of detection approximately 0.5 nm).

Routinely, all solutions are checked for detectable limits of contaminating particles; all places where particles could have contaminated the specimen, such as paraffin, are also controlled for.

Associations between talc exposure and talc particle count in the 12 exposed subjects were assessed with Spearman's rank correlation coefficient.

Results

Detailed results can be seen in Tables I and II. The mean age of the patients was 49 years (range 29 to 66

years). For eight exposed subjects, a control was found who was within 4 years of her age. Talc particle counts were not related to age in either the exposed or unexposed subjects ($p > 0.25$). The mean number of lifetime exposures for the women reporting perineal talc use was 14,820 (range 4784 to 39,312). Talc was detected in all ovaries by either polarized light or electron microscopy. There was a wide range of values, as shown by the large SDs. Table III shows that talc particles were observed to a similar extent with both exposed and unexposed subjects.

Neither the light microscopic nor electron microscopic values correlated with reported perineal talc usage (p values 0.37 and 0.45). There was a negative correlation between the values obtained by light microscopy and electron microscopy ($r = -0.34$, $p = 0.05$). An attempt to contact mothers of subjects was successful for 11 of the 24 subjects. Ten of these reported using talc to diaper their babies, which indicates that lifetime talc exposure may be underestimated for nearly all the subjects. Analyses of two fetal ovaries and a pair of surgical gloves was completely negative for talc.

In one subject we studied both ovaries; on the right side we detected no talc by electron microscopy and 556 particles by light microscopy, and on the left side we detected 1,669,000 particles per gram of wet weight by electron microscopy and 6 particles by light microscopy. Hematoxylin-eosin stained slides from the analyzed sections of tissue were examined. There was no evidence of response to talc, such as foreign body giant cell reactions or fibrosis in the tissue. Asbestos was detected in ovaries of five of the subjects with no talc exposure and in four ovaries of the talc-exposed subjects.

Comment

If transvaginal transport of perineally applied talc occurs, we would expect women with the heaviest exposures to show the largest talc particle burden in their ovaries.

Table II. Talc particle counts in women without history of perineal cosmetic talc usage

Subject No.	Age (yr)	Reported exposure history	EM talc particle count*	Polarized light microscopic talc particle counts*	Asbestos detected	Talc use with diapering
1	63	0	1,350,000	89	No	Yes
2	57	0	315,250	111	No	Yes
3	29	0	0	42	No	Unknown
4	48	0	1,669,000	6	Yes	Unknown
5	59	0	315,208	166	Yes	Yes
6	40	0	0	69	Yes	Yes
7	43	0	0	566	Yes	Unknown
8	64	0	0	420	Yes	Yes
9	49	0	0	53	No	Unknown
10	54	0	0	1139	No	Unknown
11	32	0	63,042	2200	No	Unknown
12	58	0	472,813	0	No	Unknown

EM, Electron microscopy.

*Per gram wet tissue weight.

Table III. Comparison of particle burdens between reported exposed and nonexposed subjects

Talc exposure	No. of subjects with talc by EM	No. of subjects with talc by light microscopy	Mean EM particle count*	SD	Mean light microscopic particle count*	SD
Reported talc use (n = 12)	5/12	12/12	927,416	2,174,888	190	144
No reported talc use (n = 12)	6/12	11/12	348,776	570,055	405	655

EM, Electron microscopy.

*Per gram wet tissue weight.

Tissue digestion techniques have been used to identify and quantify particle burdens of various organic materials in human tissue. The most notable use of this technique is in the identification of asbestos in the lungs of occupationally exposed individuals.^{14, 15} Other studies have examined other organs as well. In the 1979 report of Henderson et al.¹¹ ovaries were studied after an oxygen incineration procedure. They found 6900 to 55,100 talc particles per gram of wet weight in three normal ovaries, 17,400 to 24,300 in three cystic ovaries, and 6400 to 24,500 in three ovarian adenocarcinomas. No exposure histories were stated.

Our study attempted to correlate ovarian talc particle burden with exposure history. Our results do not support a linear dose-related ovarian talc particle burden. However, the mean electron microscopic particle count was much higher in talc users. Perhaps perineal talc does contribute to the ovarian particle burden; however, factors other than dosage may contribute. Other factors to consider include method of application, type of talc, and the possible contribution of inhaled talc particles. The range of talc particle values obtained in this study was wide, as evidenced by the large SDs. This spread of values was also present in the study of Henderson et al.¹¹ and in much of the asbestos fiber burden literature. Talc may be unevenly distributed throughout the ovarian paren-

chyma. This is supported by the discrepant counts we obtained on the one subject who had analysis of both ovaries. The lack of correspondence between polarized light and electron microscopy counts was due to measurement of different size particles.

Undocumented exposures to talc may partly explain the lack of correlation between adult histories of perineal cosmetic talc applications and ovarian burdens. Although both examination and surgical gloves in the past were dusted with talc, we cannot document this exposure. The gloves we currently use are talc free, according to the company and to our analyses. Ten of the 11 available mothers reported using talc while diapering their babies; this ubiquitous exposure may also contribute to the ovarian particle burdens.

Talc as a possible etiologic agent in the development of epithelial ovarian cancer may be related to asbestos exposure in several ways. Aside from the chemical similarities between the two, many cosmetic talcs contained significant amounts of asbestos, particularly before 1976.¹ Although tremolite asbestos has been documented as a contaminant of some talc preparations, the types of asbestos detected here are more commonly associated with an environmental (chrysotile) or occupational (chrysotile and crocidolite) exposure.¹⁶

The detection of talc in all the ovaries demonstrates

that talc can reach the upper genital tract. However, the quantity detected in this study did not correlate well with the reported exposure. Further study is required to elucidate whether the presence of talc in ovarian tissue is pathogenic.

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Exhibit 80

Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women

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Background: Cosmetic talcum powder products have been used for decades. The inhalation of talc may cause lung fibrosis in the form of granulomatous nodules called talcosis. Exposure to talc has also been suggested as a causative factor in the development of ovarian carcinomas, gynecological tumors, and mesothelioma.

Purpose: To investigate one historic brand of cosmetic talcum powder associated with mesothelioma in women.

Methods: Transmission electron microscope (TEM) formvar-coated grids were prepared with concentrations of one brand of talcum powder directly, on filters, from air collections on filters in glovebox and simulated bathroom exposures and human fiber burden analyses. The grids were analyzed on an analytic TEM using energy-dispersive spectrometer (EDS) and selected-area electron diffraction (SAED) to determine asbestos fiber number and type.

Results: This brand of talcum powder contained asbestos and the application of talcum powder released inhalable asbestos fibers. Lung and lymph node tissues removed at autopsy revealed pleural mesothelioma. Digestions of the tissues were found to contain anthophyllite and tremolite asbestos.

Discussion: Through many applications of this particular brand of talcum powder, the deceased inhaled asbestos fibers, which then accumulated in her lungs and likely caused or contributed to her mesothelioma as well as other women with the same scenario.

Keywords: Asbestos, Talcum powder, Chamber test, TEM, SEM, EDS, SAED, Mesothelioma

Introduction

Malignant mesothelioma occurs in both the peritoneum and in the lung pleura.¹ Mesothelioma cases have been attributed to direct occupational exposure, indirect exposure and secondary exposure.¹ A higher rate of “idiopathic” mesothelioma has been reported in women, as no link between asbestos exposure and patients has been identified.² Previous research suggests that ovarian cancer and peritoneal mesothelioma may be directly attributed to the use of talcum powder contaminated with asbestos or from exposure to partners occupationally exposed to asbestos.^{3–7} Using talcum powder in closed spaces may increase the likelihood of inhaling the powder laced with asbestos. Repeated applications increase the opportunities for inhalation and the asbestos could become concentrated in the peripheral airways and alveoli of the lungs of the talcum powder users. This has been supported by the presence of granulomas in the lungs of some talcum powder users.⁸

In 1976, Rohl and Langer tested 20 consumer products labeled as talc or talcum powder, including body powders, baby powders, facial talcums, and a pharmaceutical talc.⁶ Of the 20 products tested, 10 were found to contain tremolite and anthophyllite, principally asbestiform. The product with the highest asbestos content was the same product tested in this study. Both asbestiform anthophyllite and asbestiform tremolite were found in the Rohl and Langer tests. Given that asbestos has been determined as the primary cause of mesothelioma, it is important to note that cosmetic talc contained asbestos in the past.⁶ The contamination results from the mining process, since ore specimens taken directly from the mines have repeatedly been tested and shown to contain asbestos, most often anthophyllite and tremolite but also serpentine chrysotile asbestos.^{6,9,10}

In part from the review of corporate documents and the sworn testimony of those responsible for the sourcing of talc used in the products studied here, it was determined that three mines provided the raw material for use as talcum powder. The talc used by this cosmetic company that manufactured and

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distributed the talcum powder was from three distinct regions: the Willow Creek mine in Southwest Montana, the Regal mine near Murphy, North Carolina, and imported talc from the Val Chisone region of the Italian Piedmont.^{11–16} The specific geology of talc is an important indicator of whether a talc source may be contaminated with asbestos. These three mines all contained asbestos fibers; anthophyllite, and tremolite.^{11–18} The Val Chisone talc from Italy was studied by Pooley in 1972.¹⁸ Mine sample had intergrowths with serpentine-type, chrysotile asbestos along with tremolite and anthophyllite asbestos. The talc from Italy was named ‘American Ground Italian’ and designated as AGI 1615.^{19–21} This talc was diluted with a talc from another source to make it acceptable based on X-ray diffraction (XRD) protocols. However, it contained asbestiform tremolite and anthophyllite.²²

In this study, three laboratories analyzed a specific brand of talc from more than 50 containers of this cosmetic talcum powder product of different sizes and colors, produced over a 50-year time span to determine the presence of asbestos. The authors conducted independent product testing in unassociated laboratories in North Carolina, Georgia, and New York. A fourth laboratory, which also tested this product, will herein be referred to as Laboratory D. The lung and lymph node tissues from a woman who died from mesothelioma and testified to only using this specific brand of talcum powder were analyzed for the presence of asbestos and talc. This is the first report that explores the hypothesis that a specific brand of talcum powder coming from asbestos contaminated mines can find its way into the finished product that can be inhaled during use and cause or contribute to the development of mesothelioma

Materials and Methods

Laboratory A: product testing

In Laboratory A, over 50 containers of this particular brand of talcum powder were acquired from a variety of sources for bulk testing. Some of the containers were purchased online, while others were provided directly from the manufacturer. All of the containers were verified to be the correct brand and product.

Laboratory A tested talcum powder from each of the 50 samples using transmission electron microscope (TEM) methods. The procedure for testing by Lab A was as follows: 0.01 g of talcum powder was removed from its vial and suspended in 1 ml of distilled water with one to two drops of ethanol by brief sonication. From this suspension, 10 µl aliquots were removed and placed on a series of five formvar-coated nickel grids (100 grid openings each). In some cases, it was necessary to prepare additional sets of

five grids from the same 0.01 g sample of powder. The drops were allowed to dry in a covered Petri dish. The grids were then examined and analyzed with a Hitachi H-7000 STEM equipped with an Evex energy-dispersive spectrometer (EDS), for elemental composition and relative amounts of elements. The microscope was equipped with a tilt stage and a rotary specimen holder, which was employed with selected-area electron diffraction (SAED) analyses, as described below. Structures seen as fibers measuring at least five micrometers in length with aspect ratios of 5:1 or greater were analyzed to determine if they were regulated asbestos mineral fibers. We used EDS to chemically establish the presence of asbestos fibers and the crystalline structure was assessed using SAED. All 100 grid openings were observed and analyzed on each of the five grids for each product sample (at least 500 grid openings per sample analyzed).

Analyses were performed using a modification of the techniques described by Yamate *et al.*, and similarly adopted techniques used by the Environmental Protection Agency (EPA), American Society for Testing and Materials (ASTM), and International Organization for Standardization.^{23–26} All techniques required the use of a TEM equipped with an EDS system. Only in Yamate level III is the tilt and rotary stage optional to perform advanced SAED zone axis analysis. Yamate *et al.* stated that zone axis diffraction analysis is useful in differentiating between otherwise unidentifiable fibers.²³ In the Laboratory A analysis, zone axis analyses were not necessary as the identified amphiboles clearly demonstrated that they were asbestiform tremolite and anthophyllite confirmed by morphology, EDS chemistry, and characteristic 5.3 Å inter-row repeats on diffraction without tilting. Both asbestiform and non-asbestiform particles and fibers were present. However, in most cases this manuscript will refer to asbestiform fibers and state when they are tremolite, anthophyllite, or chrysotile type asbestos. A non-asbestos tremolite, anthophyllite will not be referred to as asbestos.

To calculate the fiber concentrations per gram of talcum powder, we first determined the number of asbestos fibers on average per grid opening. This number was multiplied by 552. The product of that equation was multiplied by 100, and then divided by 0.01 to yield the fibers/gram talcum powder value. The constant, 552, is the number of grid opening areas on the entire grid. One hundred is the number of 10 µl drops in 1 ml that the talcum powder was dispersed and the 0.01 was the weight of the talcum powder dispersed. Quality control procedures, which included testing of blanks from water, working in a clean hood environment, and working with only one

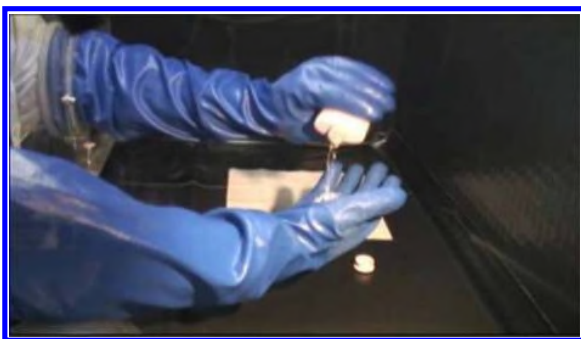


Figure 1 Pouring of powder into hands in glovebox.

sample at a time ensured that no laboratory contamination of samples.

Laboratory B: asbestos releasability testing

To determine if the user could inhale asbestos during a talcum powder application, Laboratory B assessed asbestos releasability by air sample. Air samples were generated during simulation in a glove box, consistent with normal product use in a controlled environment. These three samples included the same samples tested by Laboratory A. Environmental and personal air samples were collected using standard airborne asbestos techniques, using high-volume air pumps for environmental (stationary) samples inside and outside of the controlled area, and low-volume air pumps for personal samples taken at a distance comparable to the breathing zone of the person simulating application. Standard TEM 385 mm² effective filter area 25 mm cassettes with 0.45 µm MCE filters were used on the flow-calibrated high (7–12 l/min) and low volume (1–4 l/min) air pumps (Figs. 1 and 2).

The resulting air samples were analyzed for airborne asbestos following the analytical procedures described in the U.S. Environmental Protection Agency Code of Federal Regulations 40 CFR part 763, subpart E, Appendix A — AHERA for direct preparation of MCE filters.²⁴ All final analyses by Laboratory B were conducted on a JEOL 2000FX TEM equipped with an energy-dispersive X-ray analyzer detector and SAED at magnifications up to $\times 50\,000$, using the fiber counting criteria specified by Yamate *et al.*'s protocols.²³

Laboratory C: product bulk testing and bathroom-sized chamber releasability

Bulk methods

Laboratory C examined nine samples under an Olympus SZ-40 stereomicroscope at magnifications from $\times 7$ to $\times 40$. Portions of the particulate found in the sample were mounted in Cargille refractive index liquids for analysis by polarized light microscopy (PLM) using an Olympus BH-2 PLM with a magnification range from $\times 100$ to $\times 1000$. The PLM analysis followed the procedures for bulk analysis of building materials described by the US EPA in 1993.²⁴ Characterization of the fibers was performed using a Philips EM420 100 kV TEM equipped with an Oxford INCA EDS x-ray analysis system and capable of SAED work involving tilting of amphibole fibers. Zone axis determinations were also conducted. We used TEM asbestos fiber counting criteria of fibers greater than 0.5 µm in length with at least a 5:1 aspect ratio as described in Asbestos Hazard Emergency Response Act (AHERA) and ASTM methods: D6281, D5755,

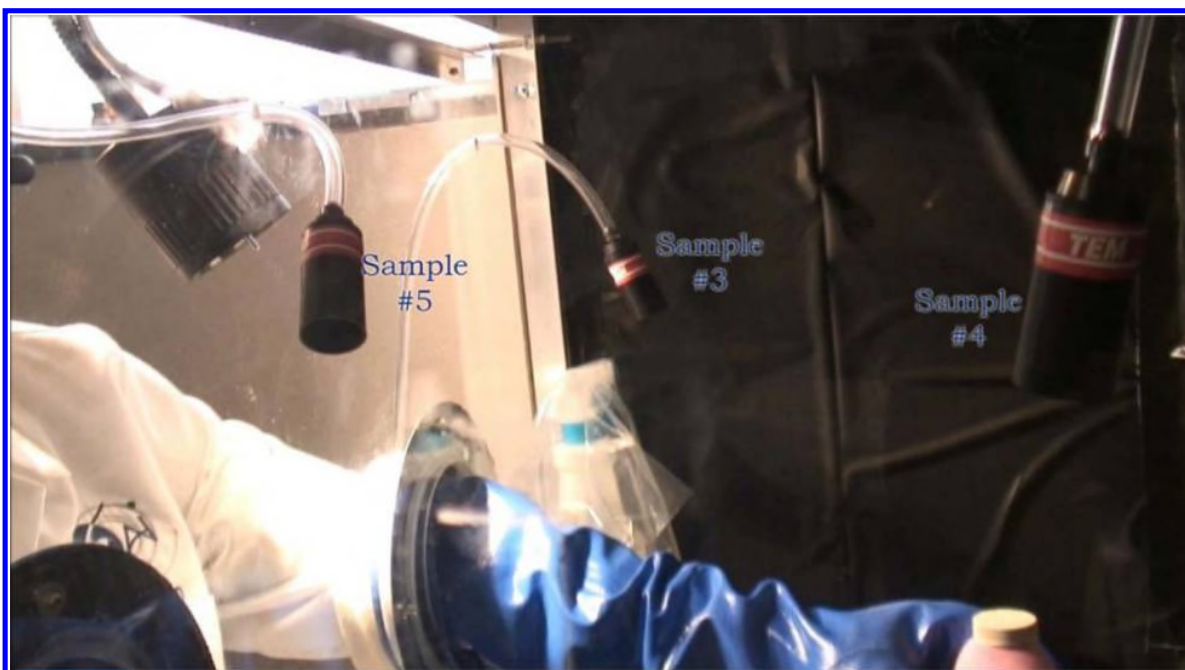


Figure 2 TEM cassettes in simulation area in glovebox.

D5756, and D648.^{24–28} Data were recorded using the ASTM D6281 format. XRD analysis was performed by an outside laboratory (DCM Science Laboratory, Inc., Wheat Ridge, CO, USA) scanning over a range of 3–45° 2 θ using 40 kV, 25 mA Cu K_{α} radiation. Mineral phases were identified with the aid of computer-assisted programs accessing a CD-ROM powder diffraction database.

Air testing

Tests to determine airborne levels of asbestos fibers resulting from application of this brand of talcum powder were performed in a testing chamber. The chamber was built to match the bathroom of the patient that used this brand of cosmetic talc. Her bathroom was measured at 7 feet, 9 inches high by 5 feet by 4 feet, 1 inch. All talc products used in these chamber tests had previously been tested in Laboratories A, B, or both.

Air test — shaker container

Using Personal Protective Equipment, a volunteer applied one of the bulk tested cosmetic talcum powders to his body using a shaker container. This particular talcum powder contained approximately 0.1% by weight and approximately 18 million anthophyllite asbestos fibers per gram. The container was weighed before and after the testing to determine the approximate weight of material applied. The talcum user wore a respirator and a bathing suit. The volunteer twisted the top of the container and shook material onto his hand. He applied the talc under his arm and around the shoulder and upper arm area. He then shook the talcum powder onto his other hand and applied it to the other underarm, shoulder and upper arm area. He shook out additional material and applied it to his neck and upper torso. He shook out and applied material two more times for a total of five applications. The total talcum application time was approximately 1 min and amounted to 0.37 g of the talcum powder. Two air samples were collected in the applicator's breathing zone at 0.5 l per minute (lpm) and two additional air samples were collected in the breathing zone at 1.0 lpm with commercial open-face air cassettes. The five-minute sampling time included the application time and a waiting period. The bystander in the test chamber had two air cassettes in his breathing zone for the five-minute period including application and the additional waiting time. The bystander wore a respirator and full protective clothing. These air samples were collected at rates of one and 2 lpm. No activities were conducted during the waiting period other than checking the pumps and cassettes. The air filters and two additional blank filters were analyzed by phase contrast microscopy (PCM) using National Institute for Occupational Safety and Health (NIOSH) Method 7400.²⁹ Two air

samples and two blanks were also analyzed by NIOSH Method 7402 via transmission electron microscopy to determine the percentage of asbestos fibers among the fibers counted by PCM.²⁹ An air sample collected from within the test chamber before the study was analyzed by a more sensitive TEM procedure following the EPA AHERA method.²⁴

Air testing puff applicator

In this test, a volunteer applied a different cosmetic talcum powder sample using a puff applicator. This particular talcum powder contained approximately 0.05% anthophyllite asbestos (approximately 70 million asbestos fibers per gram). The container was weighed before and after the testing to determine the approximate weight of material applied. The talcum user wore a respirator and a bathing suit. The talc user opened the puff container and applied the talcum powder as described above only this time with a powder puff. He then repeated the process for a total of six applications. The talcum application time was approximately 1 minute. Two air samples were collected in the applicator's breathing zone at 0.5 lpm for a sampling period of 4 minutes. One air sample was collected for a shorter period (3.3 minutes) that included the application period. Another air sample was to be collected after the application period but this sample was voided because the volunteer hit the air cassette and the cassette fell off the vacuum hose. The bystander in this test followed the same protocol as described above. Both air samples were collected at a rate of 0.5 lpm. No activities were conducted during the waiting period other than checking the pumps and cassettes. The air filters and two additional blank filters were analyzed by PCM using NIOSH Method 7400 as described above.²⁹ One air sample and two blanks were also analyzed by NIOSH Method 7402 via TEM to determine the percentage of asbestos fibers among the fibers counted by PCM.³⁰ An air sample collected from within was tested as described above by EPA AHERA method.²⁴

Human Tissue Analysis

TEM

Tissue samples from a woman with no other known exposure to asbestos other than her use of the product tested was supplied to Laboratory A. Human tissue analysis was performed according to the techniques described in Wu *et al.*²⁹ Lung and lymph node tissue was received fixed in formalin. Half of the tissue was removed from the lung and the lymph node tissue. Two grams of lung tissue were divided twice. The two halves of the lymph node weighed 0.16 g together. The two specimen types were separated throughout the study. The tissue from each was first digested in a 5% solution of potassium

hydroxide (KOH) for approximately hour at 60°C. The dissolved lung and lymph node material was then centrifuged in a high-speed centrifuge to separate the inorganic material from the dissolved organic tissue. The solute material containing the dissolved organic material and KOH was removed and distilled water was added. The inorganic material was re-suspended in the water by brief sonication. The material was re-centrifuged and the process of washing the inorganic material was performed five times. After the fifth wash, the distilled water was removed and replaced with 10 ml of fresh distilled water and the inorganic material was re-suspended by brief sonication. Ten microliter samples were removed from the suspension and placed on formvar-coated nickel grids on a metal mesh in a covered glass Petri dish to dry. Five grids were initially prepared and an additional set of five grids was prepared for each tissue type for a second analysis. The dried grids were observed with a transmission electron microscope. Four hundred grid openings on at least four grids were analyzed, and a fifth grid was used if grid openings were broken in the initial four examined grids. The fiber concentrations per gram wet weight lung or lymph node tissues were calculated from the number of fibers observed, the area analyzed, the aliquot ratio, and the total weight of the tissue sample digested.

Light microscopy

Tissue sections

Small lung tissue samples were put into 10% phosphate-buffered formalin and processed for embedding in paraffin. Five micrometer paraffin sections were cut, mounted on glass slides and stained with hematoxylin, eosin, and an iron stain. The tissue was evaluated for the presence of altered morphology and/or ferruginous bodies; two characteristics often seen in lung tissues that are a byproduct of iron-rich protein deposits on asbestos fibers resulting from macrophage frustrated phagocytosis.

Digested lung and lymph node tissue

Two hundred and fifty microliters of digested lung and lymph node material suspension used for TEM analyses was placed in a cytocentrifuge and the slides were cover slipped and observed by phase contrast light microscopy. The entire area was counted for ferruginous bodies and calculated back to the weight of the tissue to determine the concentration of bodies per gram of wet weight tissue.

Scanning electron microscopy (SEM)

SEM samples were prepared by taking 250 µl of the suspended inorganic material used for the TEM and light microscopy analyses and placed on a 0.1 µm pore size Nucleopore filter mounted on a carbon planchette on an aluminum SEM stub. The material

was allowed to dry in a covered Petri dish. The stub was then coated with vaporized carbon and observed with a Hitachi S-4300 field emission scanning electron microscope equipped with an Exev EDS system. The entire filter sample surface was scanned for fibers and asbestos bodies.

Results

All three laboratories confirmed in multiple tests the presence of asbestiform anthophyllite and asbestiform tremolite in the talcum powder products, just as had been found and described by Rohl and Langer over three decades ago.⁶

Initial bulk analyses of 50 samples of this product in Laboratory A showed that all of the samples contained asbestos fibers. Eighty percent contained only anthophyllite asbestos, 8% only tremolite asbestos, 8% anthophyllite and tremolite asbestos and 4% anthophyllite, tremolite, and chrysotile asbestos. The range in asbestos concentrations of fibers >5 µm in length were calculated to be, at a minimum, between 1840 and 1 104 000 fibers per gram of talcum powder. More than 80% of the tested cans and plastic containers contained over 10 000 asbestos fibers/gram of talcum powder. Four of the containers had less than 5000 fibers per gram and six containers had more than 250 000 fibers per gram. However, it should be noted that there were many asbestos fibers that also had aspect ratios less than 8:1. These fibers were generally found to be shorter than 5 µm and were noted, but not counted in the original product testing or in the lung and lymph node tissue testing by Laboratory A. There were also a number of fibrous talc particles that were easily distinguishable from asbestos by morphology. If there was a question regarding their identity, both EDS and SAED were employed to recognize such fibers as talc. All the fibers that were actually counted in bulk and tissue preparations were 5 µm or greater in length, with aspect ratios for the most part greater than 10:1. The majority of asbestos structures counted demonstrated aspects ratios >15:1, with many >20:1. A minimum of four fibers was identified in each sample, making the concentration determinations of asbestos statistically significant and reproducible.

Laboratory C, using PLM, TEM, and XRD, tested nine samples of the specific brand of talcum powder described above. Generally, the PLM analysis showed that the samples contained both platy and fibrous talc, less than 1% by volume of the PLM visible amphibole fibers and some quartz. The majority of the PLM amphibole particles had low aspect ratios (length to width) but some were >10:1. By XRD, one of the talcum powder samples was found to contain 4% anthophyllite. No amphibole



Figure 3 Application of powder from shaker in bathroom-sized chamber.

minerals were detected in the other eight samples by XRD. The XRD detection limit was approximately 2% by weight. In TEM analysis, all nine samples were positive for amphibole asbestos (primarily anthophyllite), and were confirmed with zone-axis electron diffraction measurements. At least five asbestos fibers per sample were recorded in each sample, with concentrations ranging from 0.004 to 0.9% by weight and from 3 to 200 million asbestos fibers per gram of fibers greater than 0.5 μm in length with at least a 5:1 aspect ratio.

Air monitoring

Releasability of asbestos into the air from the products was assessed by glove box simulation testing by Laboratory B, and by full chamber testing by Laboratory C. In a manner consistent with methods used by the EPA, NIOSH or ASTM, study product body powders and dusting powders were applied hand to hand and hand to arm. Consistent with bulk testing results, anthophyllite and tremolite asbestos was repeatedly found in the air tests resulting from these simulations (Figs. 6–8).

Shaker container test

The shaker application test used 0.37 g of talcum powder (Fig. 3). For the talc user, the average PCM fiber concentration in his breathing zone during application was 4.8 F/cc (3.1, 7.3, 3.9, and 4.9 F/cc). The asbestos to total fiber percentage as determined by TEM was 40%. Therefore, the asbestos concentration in the breathing zone of the talc user during application was 1.9 F/cc. For the bystander the PCM fiber concentration was 1.35 F/cc (0.9 and 1.8 F/cc) and the TEM derived percentage of asbestos was 35%, which results in a bystander asbestos concentration of 0.5 F/cc. No asbestos fibers were found in the sample collected in the chamber before the testing or in the blank filters.

Puff application

The puff application test used 6.25 g of talcum powder (Figs. 4 and 5). For the talc user, the average



Figure 4 Application with powder puff in bathroom-sized chamber.

PCM fiber concentration in his breathing zone during the 5-minute sampling period was 20 F/cc (23.6 and 16.5 F/cc). The asbestos to total fiber percentage as determined by TEM was 21%. Therefore, the asbestos concentrations in the breathing zone of the talcum powder user were 5 and 3.5 F/cc. The short term sample in the breathing zone of the applicator had a PCM value of 60 F/cc. Using the TEM-derived percentage of asbestos of 10%, result for the short-term sample was an asbestos concentration of 13 F/cc. For the bystander, the PCM fiber concentration was 11.7 F/cc (13.7 and 9.7 F/cc). Using the minimum TEM-derived percentage of asbestos of 36% results in a bystander asbestos concentration of 4.9 and 3.5 F/cc. No asbestos fibers were found in the sample collected in the chamber before the testing or in the blank filters.

The tests performed independently by Laboratory C using a bathroom-sized room confirmed the findings for asbestos fiber release found by Laboratory B's glovebox testing. Samples showed that significant concentrations of anthophyllite, tremolite, and occasionally chrysotile asbestos were released in the simulated application of several iterations of the products. This confirmed not only



Figure 5 Application with a powder puff in bathroom-sized chamber.

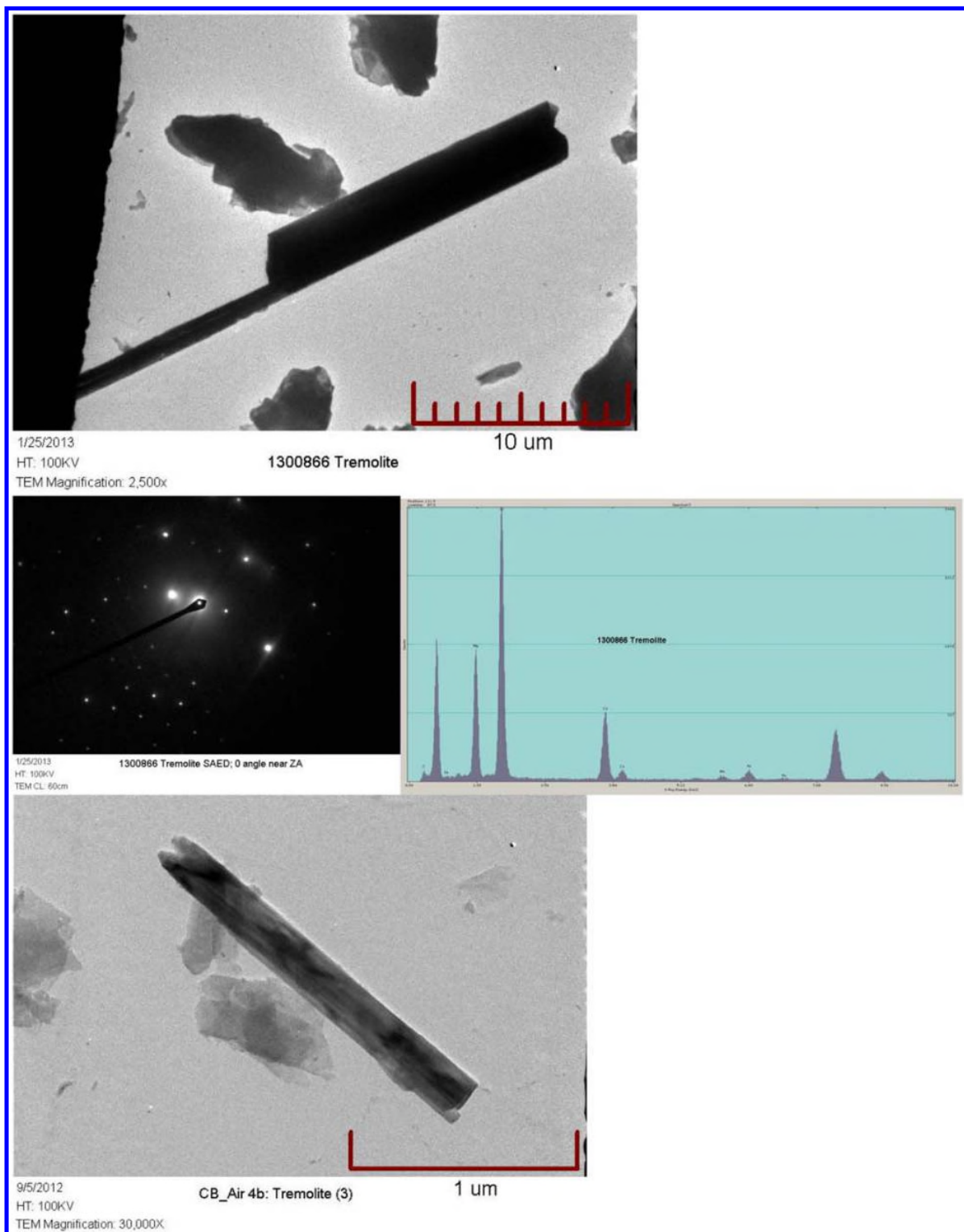


Figure 6 Tremolite asbestos from TEM analysis of releasability air testing of product (images, EDS, and SAED).

the presence of asbestos in the talcum powders, but also that the asbestos contained in the friable powders was easily aerosolized in a manner consistent with the products intended use; confirming the hypothesis that the cosmetic powders are capable agents of exposure to asbestos

Human tissue analysis

Electron microscopic analysis of the lung tissue revealed amphibole type asbestos fibers in a calculated concentration of 1380 and 4150 fibers per gram wet weight, respectively, with a limit of detection of 690 fibers per gram wet weight. All fibers counted

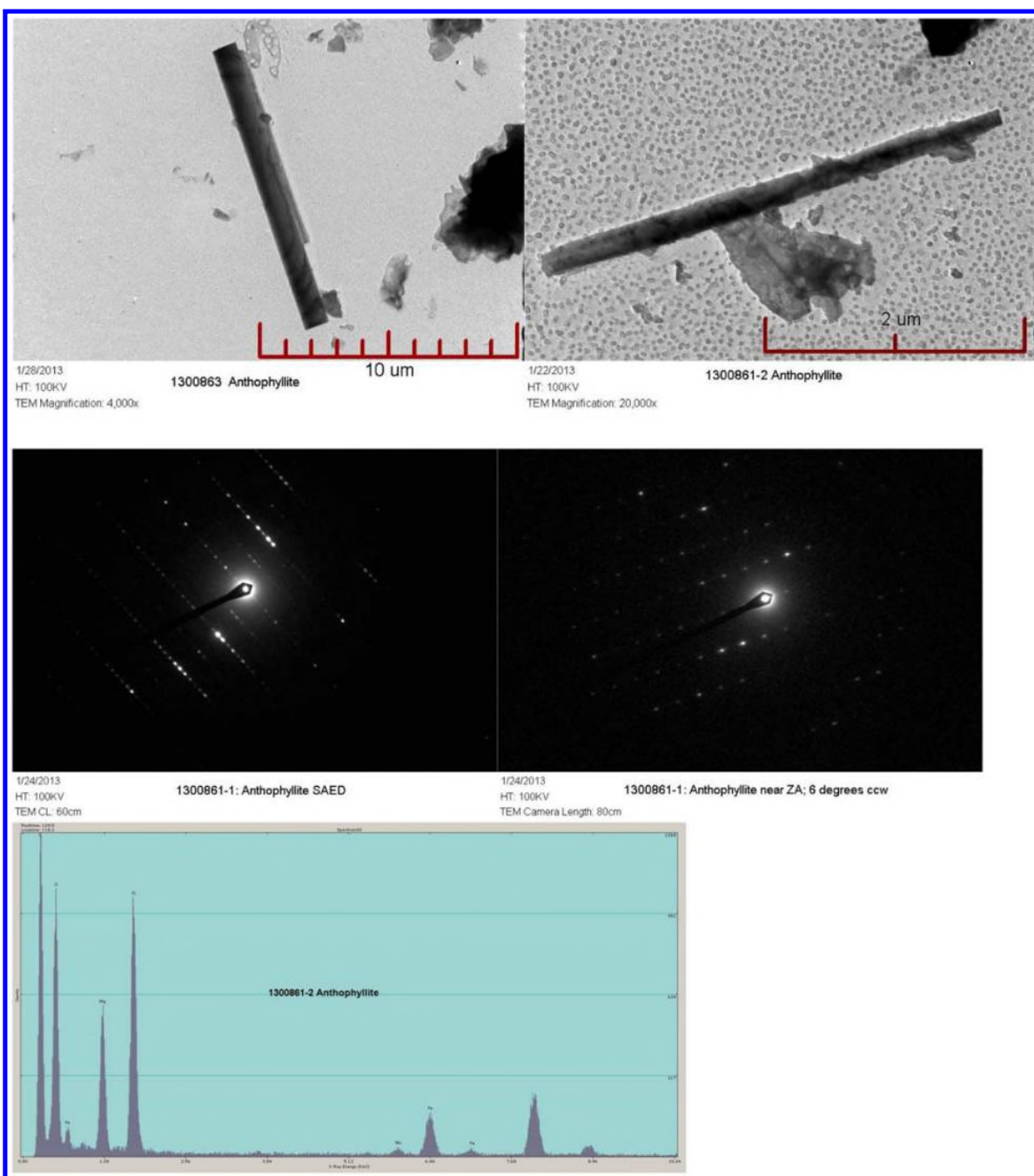


Figure 7 Anthophyllite asbestos from TEM analysis of releasability air testing of product (images, EDS, and SAED).

were 5 µm or greater in length and had aspect ratios of 20:1 or greater. The amphiboles were identified by EDS and SAED analysis as anthophyllite (Fig. 9) and tremolite (Fig. 10) asbestos. The asbestos fibers were seen in a ratio of 1:1 and 2:1, respectively (anthophyllite/tremolite). There were many anthophyllite and tremolite asbestos fibers less than 5 µm in length that were not counted. The majority of these smaller asbestos fibers were of the anthophyllite type. Light microscopic analysis of the cytocentrifuge preparation revealed a calculated concentration of 140 asbestos bodies per gram wet weight of lung

tissue by phase contrast light microscopy in both samples.

Electron microscopic analysis of the lymph node tissue revealed amphibole asbestos fibers in a calculated concentration of 12 738 fibers per gram wet weight, with a limit of detection of 2123 fibers per gram wet weight. All counted fibers were at least 5 µm in length with aspect ratios of 10:1 or greater. The amphiboles were identified by EDS and SAED analysis as anthophyllite and tremolite and they were seen in a ratio of 5:1 anthophyllite/tremolite. There were many anthophyllite and tremolite fibers less

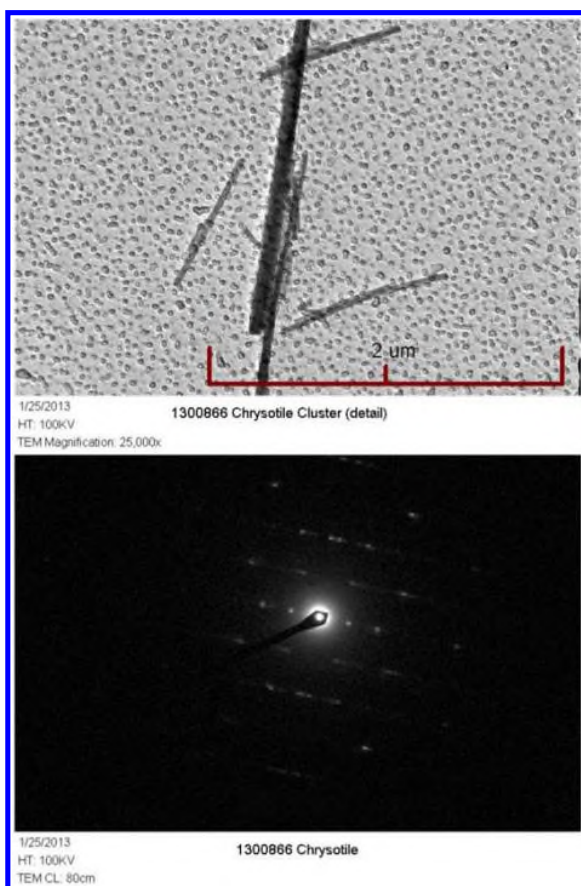


Figure 8 Chrysotile asbestos from TEM analysis of releasability air testing of product (image and SAED).

than 5 μm in length that were not counted. We also observed but did not count tremolite cleavage fragments. Light microscopic analysis of the cytocentrifuge preparation revealed a calculated concentration of 92 asbestos bodies per gram wet weight of lymph node tissue by phase contrast light microscopy (Fig. 11).

Histological sections of the tissue showed focal areas of mild parenchymal fibrosis and a more generalized pleural fibrosis. Although many ferruginous bodies were identified in the cytocentrifuge preparation, most were relatively small and not seen in the H&E-stained paraffin sections. These macrophages were clustered and contained a combination of fibrous and platy talc and small asbestos bodies.

In addition to the fibrous and platy talc described above, other inorganic materials were seen. Aluminum silicates and magnesium aluminum silicates in both fibrous and platy form were identified. We elected not to count these fragments. Their presence supports the hypothesis that the lung and lymph node samples match findings from the tested talcum powder.

The two analyses performed on the lung tissue were from two separate tissue digestions. The second was prepared with tissue not previously analyzed, but

saved from the original half of the tissue retained by Laboratory A. The results proved to be completely reproducible with no finding of any additional fiber types other than those reported above.

Confirmation of interlaboratory analyses

After several years of independent testing in separate laboratories, the authors became aware of one another's work through litigation. The finding that this historic brand of cosmetic talcum powder contained asbestos fibers with generally the same morphological and chemical assemblage was confirmed. A fourth laboratory (Laboratory D) tested many of the same samples, but did not report asbestos findings. Owing to the inconsistency with the other laboratories, re-examination of results from Laboratory D was warranted.

Two of the three authors of this study went to the Laboratory D and were supplied with the prepared filters on TEM grids or SEM stubs previously analyzed by Laboratory D. They were also supplied with both TEM and SEM microscopes to re-analyze the specimens, along with data and locator sheets, allowing for the same grid openings and areas to be observed as in the initial analyses.

Reanalysis of subject product samples

One author re-analyzed the TEM preparations of 20 study products of talcum powder prepared by Laboratory D. Asbestos structures were found in the re-analysis, some of which were named in the original analysis as cleavage fragments, intergrowths, or fibrous talc rather than as asbestos. Although the author-reviewer agreed with many of the non-asbestos fibers identified, he concluded the original analyses were incomplete. Additional analyses by the author-reviewers showed some of the incompletely analyzed fibers to be asbestos. In other cases, asbestos found on re-analysis was located on areas of the filter where no fibers were recorded in the original bench sheets or reports. In some instances, the overall distribution of particulates on the preparations was inhomogeneous, in contrast with the method of choosing grid openings for the original analysis by skipping every other opening in a "checkerboard" fashion. Furthermore, the methods named on the analytical count sheets were not the same as the methods cited in the reports from Laboratory D.

Laboratory D reported no asbestos fibers in the 20 samples analyzed. In contrast, asbestos fibers were identified in all 20 of the same products in Laboratory A and in 16 of 20 products tested by Laboratory B. In the re-analysis of those same 20 samples originally analyzed by Laboratory D via TEM, eight were found to contain asbestiform anthophyllite, six asbestiform tremolite, and two were found to contain chrysotile fibers. These findings were significant because re-analysis was not a

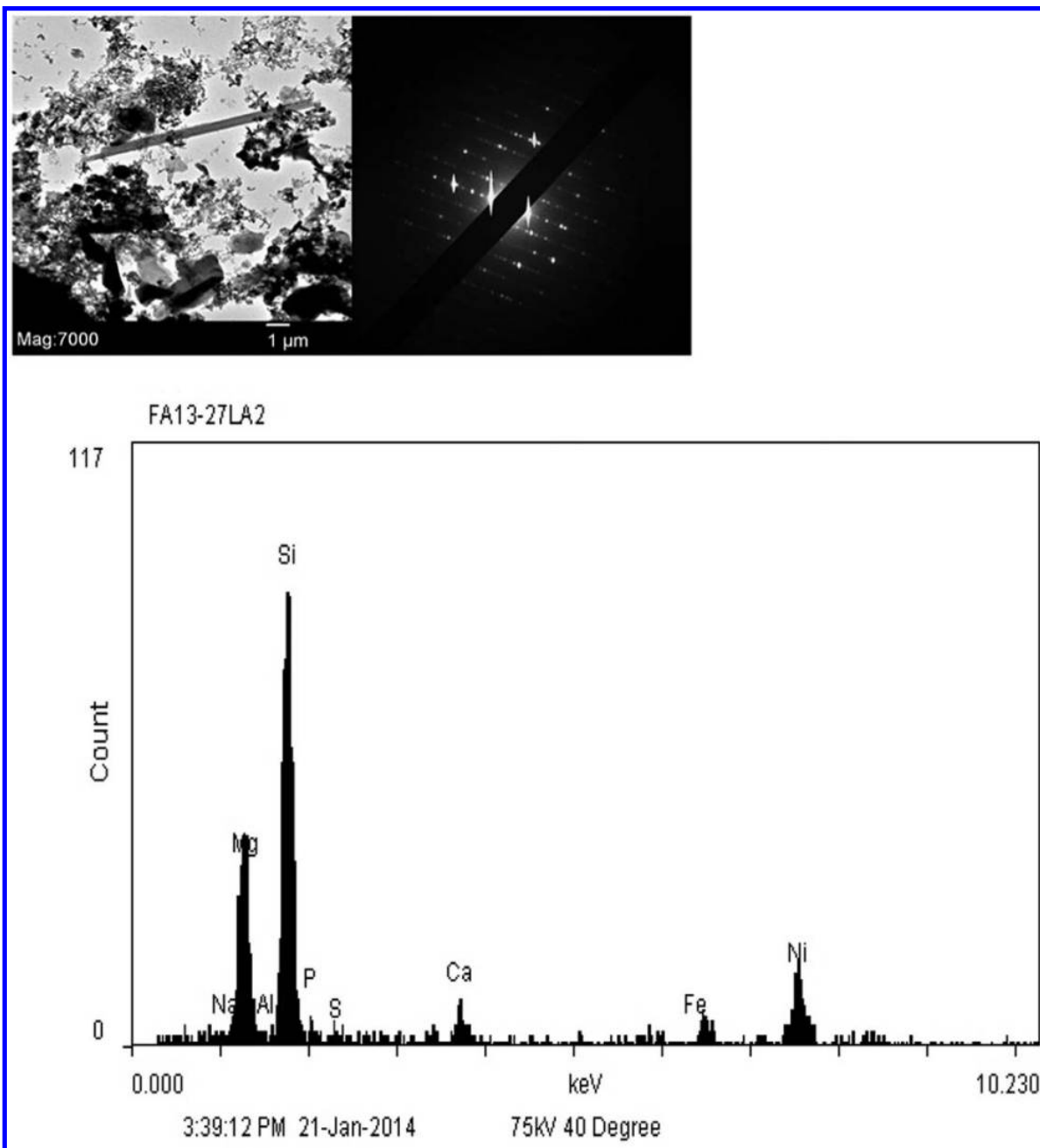


Figure 9 This asbestos fiber is a representative sample removed from the lung tissue of the patient exposed to cosmetic talcum powder. Anthophyllite asbestos fiber is observed and its SAED pattern is demonstrated beside it with the EDS spectra.

complete replication of the original analysis due to time constraints, damage, or unsuitable preparations. It was apparent that the technicians in Laboratory D missed fibers and misidentified asbestos fibers as non-asbestos.

Re-analysis of human tissue

Laboratory D also performed fiber burden analysis on human tissue with differing results than the study of the authors. Similar to the re-evaluation of bulk analyses, two author-reviewers analyzed the human tissue sample preparations of Laboratory D together and found significant differences in their analyses compared to the technicians who originally analyzed

the grids and stubs. We determined that the technicians misidentified anthophyllite asbestos fibers that had been coated with iron and protein (anthophyllite asbestos bodies) as either cleavage fragments or as amosite fibers (Fig. 12). Furthermore, it is the authors' consensus that there are no generally accepted criteria to classify individual fibers as cleavage fragments by TEM when the sample contains attributes of an asbestos fiber or countable structure. When Laboratory D technicians initially looked for asbestos bodies to determine the fiber core, they concluded that most were amosite. However, when the two author-reviewers examined

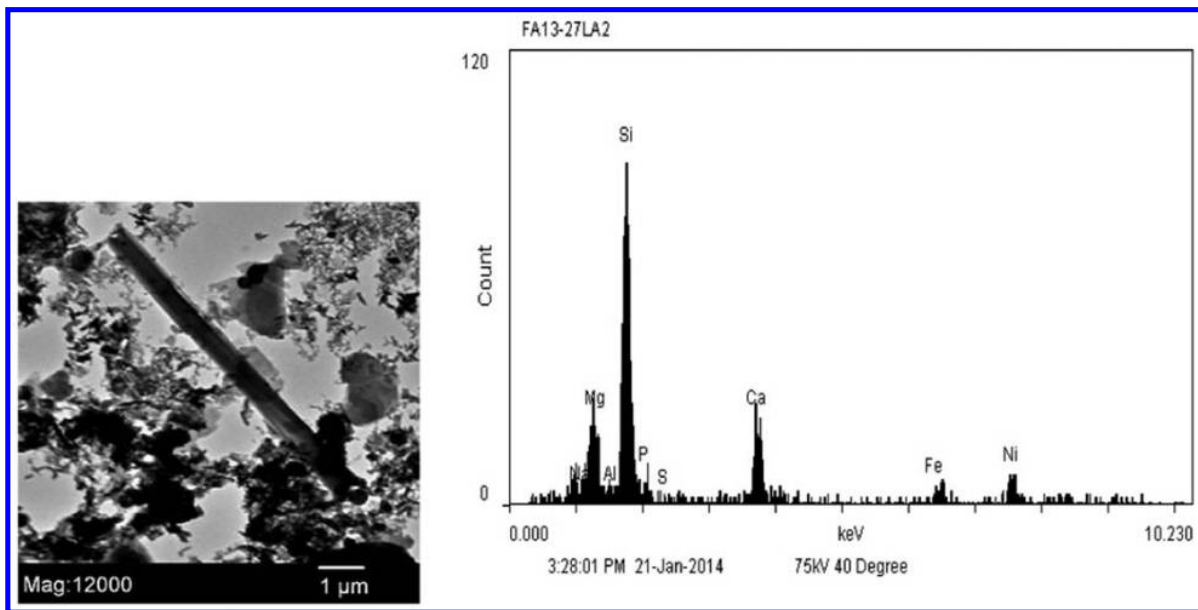


Figure 10 This asbestos fiber is a representative sample removed from the lung tissue of the patient exposed to cosmetic talcum powder. Tremolite asbestos fiber with its corresponding EDS spectra.

the same structures, it was clear that the cores were either anthophyllite or could not be determined because there was exposed fiber core. In previous studies of human tissue having anthophyllite and anthophyllite bodies (Fig. 11), it was common to find that the entire anthophyllite core, even if quite long, was completely coated.

Zone axis confirmation in bulk, tissue, and air
Laboratories A, B, and C confirmed original amphibole asbestos structures by zone axis diffraction. Laboratories A, B, C, and D re-analyzed archived preparations with the intent of confirming amphiboles by zone axis diffraction. In all four sets of re-analyzed preparations, anthophyllite and tremolite asbestos were consistently

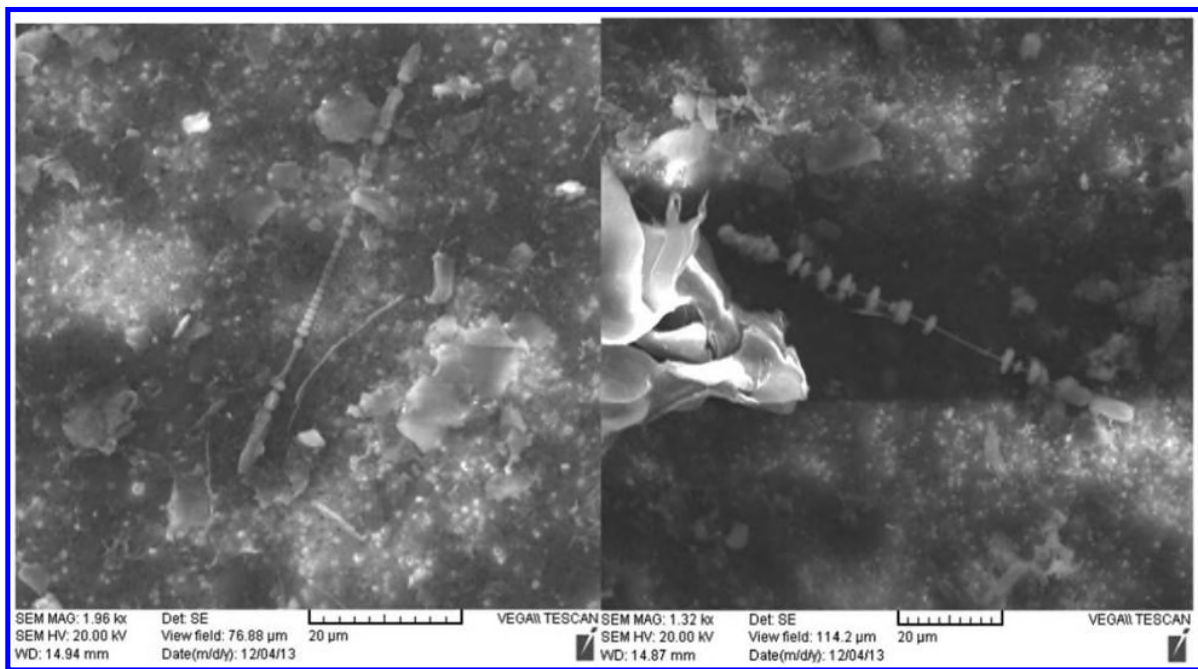


Figure 11 These are asbestos bodies from the patients lung tissue taken by SEM. It is possible to see in the one to the left that the fiber is almost completely covered by the iron protein coating. This is compared to the one at the right which appears to have much more fiber exposed. However, upon EDS testing, it was determined that in both cases, these were anthophyllite fibers and they were both entirely coated, although much thicker in some areas as opposed to others.

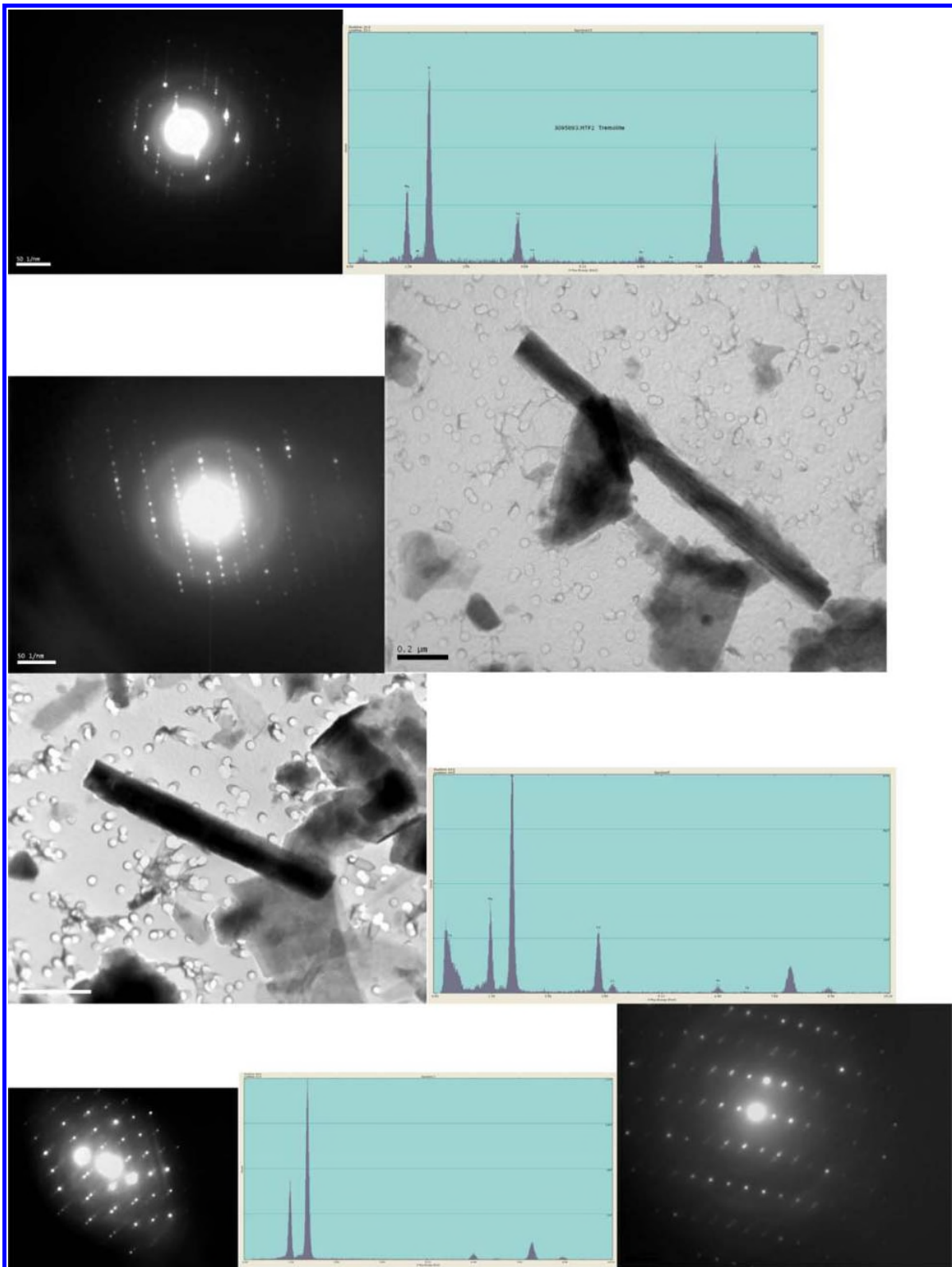


Figure 12 Tremolite and anthophyllite asbestos from re-analyses of 'Lab D' preparations (images, EDS, and SAED).

confirmed by zone axis diffraction pattern measurements. This included confirmation of asbestiform amphiboles, including anthophyllite and tremolite asbestos

from the original product testing, from the releasability air tests, and from TEM preparations of lung and lymph node tissues.

Discussion

Historically, many mesotheliomas, particularly abdominal mesotheliomas in women, have been labeled idiopathic due to a lack of an identifiable source for asbestos exposure. Further, there has been an increase in the number of idiopathic pleural and abdominal mesotheliomas in women using this specific brand of talcum powder. There have been a few studies that have examined talcum powder and its potential to cause ovarian tumors.^{3–5} The studies were inconclusive, but suggested that talc, asbestos, or both may cause these cancers through vaginal exposure.⁴ These studies attributed asbestos found within the women's lesions to result from contact with their partners. There was no consideration for the potential of the asbestos being a contaminant in the women's talcum powder.^{3,4} However, it has been reported that cosmetic talcum was contaminated with asbestos, and that asbestos was found in the mines from which the talc originated.^{6,9} Our findings indicate that historic talcum powder exposure is a causative factor in the development of mesotheliomas and possibly lung cancers in women.

Talc has been identified as a causative for mesotheliomas in New York talc miners.³¹ In recent years, more than 10 women developed mesothelioma and their only source of asbestos exposure was the use of one brand of talcum powder. This study demonstrates that the brand of talcum powder tested contained asbestos. Furthermore, we have traced the asbestos in the talc to the mines from which it originated, into the milled grades, into the product, and finally into the lung and lymph nodes of the users of those products, including one woman who developed mesothelioma.

Based on the testing and re-testing conducted by the authors, it is evident that this product line has been consistently contaminated with asbestos tainted talc derivatives. The amount of asbestos was variable based on the time of manufacture and the talc source. There have been numerous publications that have indicated that the talc in many talc deposits had asbestos contamination.^{32–35} The most common types of asbestos were tremolite and anthophyllite. These are the same asbestos fiber types found in the autopsied lungs and lymph nodes tested here for asbestos presence. In a few containers tested in this study, chrysotile was also found, consistent with the source ore geology.

Most, if not all, testing of cosmetic talc was performed using techniques designed for light microscopy, PLM, or by TEM criteria designed to test air and water samples. Testing determined if asbestos levels were above the EPA standards under AHERA or the Occupational Safety and Health Agency standards. These protocols are based on the parameters described

in the Yamate method.²³ There are significant limitations to these methods. PLM analysis misses small fine asbestos fibers or fibrils because the limits of the resolution are approximately 0.2–0.5 μm for different forms of light microscopy. Based on our findings, approximately 90% of the fibers identified fall into this category. Determining the number of TEM grid openings to be counted during the analysis requires stopping factors, or limits on the quantity of analysis to be performed. The Draft Yamate method (1984) gives the guidelines of “100 fibers or 10 grid openings, whichever is first.”²³ This counting rule was instituted for cost limitation purposes. The Draft Yamate method describes that while this guideline of using 10 full-grid openings represents a judicious compromise between a reasonable experimental effort and a fairly low value of the detection limit, the analysis of additional TEM grid openings reduces the detection limit and improves the precision of the estimates. In the talc study described here, a very low level of detection was desired and therefore, in some cases, as many as 500 plus grid openings were analyzed to reduce the detection limit and improve sensitivity of the test. TEM testing has been adequate for evaluating building material asbestos abatement projects, local air sampling, and potential water contamination with asbestos.²³ However, these criteria are not acceptable for assessing asbestos fiber burden analyses in human tissues and for low asbestos content products that are used intermittently in small quantities over long periods of time, such as cosmetic talcum powder.³⁶ Talc related asbestos exposures can be heavy at times, above 4000 F/cc. The inhaled asbestos fibers are extremely variable in the causation of asbestos related tumors and fiber burdens found in the deceased woman were within the reported ranges for amphiboles to be causative factors in the development of such a tumor.³⁷

Therefore, it is imperative to analyze products such as talcum powder for small amounts of asbestos fibers. This requires that the limits of detection be lower than levels required in a typical Yamate analysis. The author-reviewers observed that the Laboratory D analyses were done using Yamate methodology and no more than 10–25 grid openings on bulk TEM grid preparations were observed.²⁴ Based on Laboratory D's protocols for testing, millions of fibers/gram of talc would have to be present in order to find fibers. Lower concentrations in the ranges found by Laboratories A, B, and C demonstrated that fibers were detectable and present at levels sufficient to cause mesotheliomas.

Although long narrow asbestos fibers are highly carcinogenic, shorter, narrow fibers are also dangerous.^{36–38} It is now more common to find shorter narrow fibers in human tissue digestions than long narrow fibers, especially for chrysotile.³⁹ This

study provides evidence that low concentrations of asbestos in raw materials do not necessarily correlate to low health risk.^{38,39} Examples of recent studies of low asbestos content producing significant airborne concentrations in simulated activity include activity-based monitoring of asbestos as it naturally occurs in several sites, as conducted by the EPA and Agency for Toxic Substances and Disease Registry, and vermiculite-containing attic insulation studies.⁴⁰ These studies have repeatedly shown that substantial airborne concentrations could be derived from materials with only a fraction of a percent asbestos content.³⁶ This has been especially true when a product was in a friable state, or where the obvious use of material intimates aerosolization of fibers. Significant airborne concentration can be easily generated from such conditions when asbestos is a constituent.^{40–43}

The talc application studies were simulations of exposures to talc used by a deceased woman who had mesothelioma. The air volume in the testing space was 158 cubic feet. This is in the range of the chamber sizes used by talcum powder manufacturers in the 1970s in their studies of the quantity of talcum powder used in normal application. The space used by Russell was 171 cubic feet and the space used by Aylott was between 152 and 163 cubic feet. The amount of material used in the shaker test was 0.37 g. The amount used for the puff applicator test was 6.25 g.^{44,45} The shaker test was a light application and the puff a heavy application. However, the heavy application was within the ranges published by Russell of 8.84 ± 8.32 g and Aylott of 2.5 ± 12.5 g. The “talcing times,” or the duration of talcum powder application, were approximately 55 seconds for the shaker test and approximately 57 seconds for the puff applicator test.^{44,45} These were within the ranges published by Russell of 83 ± 33 seconds and Aylott of 28–78 seconds for adult dusting.^{44,45} Laboratories A and B determined that the contaminated talcum powder released inhalable asbestos into the air.

Another issue in this study was the documentation and identification of cleavage fragments. The scientific community has not generally adopted cleavage fragment differentiation criteria.⁴⁶ It is unclear how to identify a cleavage fragment once the stone or material has been finely ground. Two criteria for distinguishing cleavage fragments from asbestos fibers have been proposed. The first is that the ends of cleavage fragments have oblique angles and second is that the aspect ratios are all less than 20:1. The ends criterion has not been validated with known asbestos/cleavage fragment standards and while an aspect ratio of 20:1 suggests that a fiber is likely to be an asbestos fiber, some fibers with aspect ratios below

20:1 are also asbestos. As the fiber aspect ratio increases, the percentage of asbestos fibers versus cleavage fragments also increases.⁴⁷ However, this criteria falls short when the fiber is extremely thin and is the smallest unit of diameter of a fiber. When these small fibers are removed and analyzed from human tissue, these criteria have to be discarded because enzymes with basic and acidic molecules within cells can leach elements from the surface, causing a breakdown of the fibers, especially when thin in diameter. van Orden *et al.* propose criteria to identify cleavage fragments by SEM.⁴⁶ The criteria are based on surface contours which identify a cleavage fragment.⁴⁶ However, this method has not been verified and is not generally accepted. There were no photographs of TEM or high-resolution high-magnification SEM provided by Laboratory D, which classified potential asbestos fibers as cleavage fragments

In conclusion, we found that a specific brand of talcum powder contained identifiable asbestos fibers with the potential to be released into the air and inhaled during normal personal talcum powder application. We also found that asbestos fibers consistent with those found in the same cosmetic talc product were present in the lungs and lymph node tissues of a woman who used this brand of talc powder and developed and died from mesothelioma.

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Exhibit 81



DETERMINATION OF TOXIC HEAVY METALS IN DIFFERENT BRANDS OF TALCUM POWDER

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ABSTRACT

Talcum powder is a cosmetic product made from finely ground talc, an extremely soft mineral. One of the most common uses of talcum powder is in baby care, Talcum powders are widely used all over the world to keep the body dry due to sweat, for fragrance and for beauty purposes. The present research work is done for the determination of heavy metals like Cd, Co, Pb, Cu and Cr in 30 different brands of talcum powder. Determination of heavy metals was done by atomic absorption spectrophotometer and pretreatment of samples was done by acid digestion by using Conc. HNO_3 and H_2O_2 . The lead contents in all brands were in the range of 0.0006-1.05 ppm, while cadmium contents were in the range of 0.001-0.080 ppm and chromium contents were 0.08-0.35 ppm, copper contents were 0.07-0.35 ppm, cobalt contents were 0.003- 0.180 ppm ranges were present. The lead concentration was extremely high in all brands followed by the cadmium. Cadmium concentrations were low in all brands. All the metals are present within safe limits in under study all the brands.

KEYWORDS: Acid Digestion, Atomic Absorption Spectrometer, Heavy Metals Talcum Powder, Toxic

INTRODUCTION

Skin is thought to be the largest organ of our body and has many important functions. As the primary interface between us and our environment, the skin serves several distinct functions which are protection, sensation, thermoregulation and communication. Skin is also self-repairing after injury. A long time ago it was thought that skin is impermeable barrier but now a day we know it differently. Substances that come in contact with skin are penetrating and ultimately find their way in the bloodstream. Toxins and other harmful products accumulate into the fundamental organs over a period of time causing many problems in bodies [1]. Because the skin having the property of absorbing the thing so anything which is applied on the body comes into contact with skin and penetrate into the body. Likewise when powder is applied on body to keep the body dry due to sweat then the harmful thing present in it penetrate into the body [2]. Some of the harmful compounds are soluble in water they dissolve in the sweat and penetrate into body. Talcum powder comes in direct contact with only our skin and causes many skin problems and babies sometimes inhale it then they have to suffer the problem of inhalation. Out of 35 heavy metals some are useful for our health but in small quantities and the higher quantity of these metals becomes harmful for our health [3]. Other than these useful heavy metals are dangerous to our health their small quantities are bearable and show no effects on the body. But higher quantities are much dangerous for human health [4].

In trace amounts some heavy metals are essential for a healthy life. These heavy metals are present in our body in trace amounts e.g. Fe, Mn, Cu and Zn. These heavy metals are present in our food stuff, in vegetables and fruits. In industries the heavy metals have much importance as these are used in manufacturing of dyes, steel, alloys, batteries and much more. Many products of these in our daily life and add to quality of life when used properly [5]. These trace metals are of biological importance in trace quantities. But the large quantities of these metals are of main concern. So the

need of proper understanding about the amount and oxidation states of these metals are of much importance [6]. Heavy metals when are not metabolized by body and gathered in soft tissues of our body then they become toxic. Heavy metals are entered into body by inhalation, ingestion and absorption through the skin when humans become in contact with heavy metals in industrial and agricultural environments. The most common way of heavy metal exposure is by industrial environment through inhalation in adults. In children the most common route of exposure is ingestion.

Increasing industrialization in the world is the main cause of heavy metal pollution [7]. The Agency for Toxic Substances and Disease Registry (ATSDR) has formed a list in 2001 known as “Top 20 Hazardous Substances” in collaboration with the US Environmental protection Agency. The heavy metals are in this list due to their hazardous effects. Arsenic, Lead and Mercury are ranked at 1st, 2nd and 3rd in the list. Researchers done this study to check the presence or absence and the quantity of these toxic metals in collected talcum powder samples by using Atomic Absorption Spectrometry (AAS). The concentration of heavy metals is to be measured in ppm. The resultant values are compared with the tolerable values given by World Health Organization (WHO) [6]

Cosmetics are the products use for the personal care and change the look of our face and body. Cosmetics are used for personal hygiene and for beauty purposes since start of civilization. It is a part of our routine life and these are not only used by the upper class of the society but also used by the middle and low class of the society. Recently there is a great change in cosmetics industries have been seen by the production of cosmetics of various types for beauty and care purposes.

These products are produced for the beauty purposes of hair, skin, nails, teeth and body [8] Cosmetics include: Creams, hair oils, Hair dyes, Kajal, Lotions, Perfumes, Lipsticks , Talcum powders, Face powders. Beauty consciousness of the people has increased the demand of beauty products in the market. As the demand of cosmetics increased the side effects of cosmetics also come forward due to the use of these [9]. Cosmetics are used to keep the beauty of body parts and give fragrance. The side effects of cosmetics are the main cause of attention of the researchers and clinician to check out the probable reason behind these side effects. Due to use of cosmetic products users observe the skin irritation and skin allergy type problems so the researcher find out the reason of these problems. Then they reach to the problem that it caused due to the heavy metals present in beauty products. Heavy metals contamination is one of the main causes for these side effects of cosmetic products.

Talc is an important industrial mineral. It is hydrated magnesium silicate. Talc is an important industrial mineral. It is hydrated magnesium silicate and its chemical formula is $\text{H}_2\text{Mg}_3(\text{SiO}_3)_4$. Talc is an important industrial mineral. It is hydrated magnesium silicate. Talc name is derived from an Arabic word *talq*, meaning “pure.” Talc is naturally occurring pearly white mineral and it found in deposits all over the world. Now a day’s talc is used in many different industries and used in consumer products like plastic, lubricants, paints. Talc is an important raw material for the manufacturing of talcum powder. Talc contains 4.8% H_2O , 31.7% MgO , 63.5% SiO_2 . Talc is a secondary mineral manufactured by the metamorphism of the different rocks. Talc is used in many industries as it is the softest mineral on this earth. Due to its softness it is used in many industries.

Talc is not present on the earth but it is manufactured by the magnesium rocks through different reactions. In anything in which talc mineral is present it is known as talcum. Talc has property of absorbing moisture so it is also used on places where we want to keep the place dry [10]. Talcum powder is the source of talcosis disease. Talcosis disease occurred due to the abundant use of talcum powder Talcosis is a silicate induced disease of lungs. It is mostly found in the people which are exposed to the talc and also experienced in the peoples using cosmetic talcum powder in excess.

MATERIAL AND METHODS

Study Plan

An experimental process of research was done to evaluate the presence or absence of heavy metals in different samples of talcum powder collected from local market; and the concentration of each heavy metal which present in the samples [6].

Collection of Samples

Most popular thirty samples of different brands of talcum powders widely used in Faisalabad were purchased from cosmetic shops, open markets and super markets in and around towns and cities around Faisalabad. Total thirty different brands are of thirty different manufacturing companies. The talcum powder brands studied are: Black cat, D&S Products, Black Beauty, Medicam Valentine, White Lily, Nisa Floral, Blue Diamond, Olivia, Touch Me, Medora, Wild Flower, Max Lavander, Mother Care, Genny Energetic, Johnson's baby powder, Dove, Poison, Goree black, Tibet, Havoc, Corel, One Man Show, Follow Me, Enchanter and Sensation.

Sample Preparation for Analysis

Preparation of samples for heavy metal analysis was done by standard procedure. Each of talcum powder samples was analyzed by using the acid digestion protocol.

Preparation of Powder Samples for Analysis

Following method was followed for the wet digestion of the collected talcum powder samples. Accurately weighed powder samples (1g) were placed in digestion flasks and concentrated nitric acid (10 ml) was added. The digestion flasks were heated (70 to 80 °C) on a hot plate for 30 minutes. After cooling, 5 mL of H₂O₂ was added in the flasks and heated vigorously till the white fumes appeared and mixture volume reduced to 2-3 ml. Finally, the contents were diluted up to desired volume by adding de-ionized water.

RESULTS AND DISCUSSIONS

The concentration of heavy metals was determined by atomic absorption spectrometer. Metals are essential nutrients due to their functioning in metabolism. Metal play an important role in many enzymes, as antioxidants and catalysts in human life [11].

Some of these trace elements like manganese (Mn), cadmium (Cd), chromium (Cr), zinc (Zn) and copper (Cu) are necessary micronutrients and perform various types of biochemical functions in all living organism. Humans need a specific amount of micronutrients like Zn and Fe, but excess uptake of non essential metals like Pb and Cd can be highly harmful. Living beings cannot synthesize minerals element, these are usually required through food [12].

The present research work is focused on the determination of concentration of heavy metals in talcum powder brands. Table 1 tells about the mean concentration of lead, cadmium, cobalt, chromium and copper. It also tells about the standard deviation in the readings.

Heavy metals are common contamination in various brands of talcum powder. Heavy metals cause many problems in our body like pain, unconsciousness, and stomach problems. Heavy metals present in the talcum powder are come from the contaminated environment where it manufactured. Heavy metals come from the fragrant materials added in talcum powder. In present research work the heavy metals are determined by AAS in this technique the heavy metals are determined qualitatively and quantitatively. Quantity of heavy metals is determined in ppm. There are many of heavy

metals are present in cosmetic talcum powder and the manufacturers also don't know about these heavy metals. There are some heavy metals and their effects

Cadmium is a heavy metal which is present in talcum powder. The safe limit of cadmium is 0.9ppm to 3ppm. When a large amount of talcum powder is inhaled then the amount of heavy metal is also becomes high in the body. Cadmium higher concentrations are harmful for the health and the target organs of cadmium are bones, brain and nervous system. Figure 1 shows the amount of cadmium in 30 different brands of talcum which is in the range of 0.001-0.080 ppm. This concentration is in the safe limit.

Cobalt is a heavy metal present in talcum powder. The safe limit of cobalt is 1 ppm. The target organs of cobalt are kidney, brain and bones. When cobalt value becomes high then it effects the functioning of different organs of human beings. Figure 2 shows about that the concentration of cobalt in different brands of talcum powder present in the range of 0.003- 0.180 ppm.

Figure 3 shows the concentration of chromium in the talcum powder brands. Chromium is a heavy metal present in talcum powder it is harmful in small amounts for the human beings. The safe limit of chromium is less than 5ppm. This is really harmful for infants if they inhaled it along with talcum powder. The concentration of chromium is present in the range of 0.08-0.35 ppm

Table 1: Concentration in ppm of Heavy Metals in Different Brands of Talcum Powder by Mean \pm Standard Deviation

Sample	Pb	Cd	Co	Cr	Cu
P1	0.016 \pm 0.005	0.013 \pm 0.006	0.013 \pm 0.005	0.127 \pm 0.005	0.35 \pm 0.001
P2	0.203 \pm 0.130	0.001 \pm 0.001	0.023 \pm 0.005	0.22 \pm 0.01	0.226 \pm 0.005
P3	1.053 \pm 0.056	0.08 \pm 0.01	0.02 \pm 0.01	0.14 \pm 0.01	0.286 \pm 0.015
P4	0.001 \pm 0.001	0.006 \pm 0.005	0.013 \pm 0.006	0.24 \pm 0.01	0.25 \pm 0.01
P5	0.166 \pm 0.005	0.003 \pm 0.005	0.023 \pm 0.006	0.123 \pm 0.006	0.146 \pm 0.006
P6	0.16 \pm 0.008	0.023 \pm 0.005	0.007 \pm 0.005	0.187 \pm 0.006	0.286 \pm 0.005
P7	0.013 \pm 0.005	0.033 \pm 0.005	0.01 \pm 0.001	0.26 \pm 0.01	0.19 \pm 0.001
P8	0.24 \pm 0.029	0.013 \pm 0.005	0.001 \pm 0.001	0.11 \pm 0.01	0.216 \pm 0.005
P9	0.001 \pm 0.001	0.001 \pm 0.001	0.016 \pm 0.001	0.30 \pm 0.01	0.213 \pm 0.005
P10	0.011 \pm 0.008	0.03 \pm 0.001	0.013 \pm 0.005	0.237 \pm 0.005	0.227 \pm 0.006
P11	0.163 \pm 0.005	0.013 \pm 0.006	0.003 \pm 0.006	0.157 \pm 0.006	0.186 \pm 0.005
P12	0.047 \pm 0.005	0.013 \pm 0.006	0.013 \pm 0.005	0.127 \pm 0.006	0.11 \pm 0.01
P13	0.38 \pm 0.008	0.02 \pm 0.01	0.013 \pm 0.005	0.146 \pm 0.006	0.21 \pm 0.01
P14	0.001 \pm 0.001	0.016 \pm 0.005	0.013 \pm 0.005	0.143 \pm 0.006	0.183 \pm 0.005
P15	0.013 \pm 0.005	0.033 \pm 0.005	0.027 \pm 0.006	0.35 \pm 0.01	0.08 \pm 0.01
P16	0.08 \pm 0.008	0.001 \pm 0.001	0.09 \pm 0.01	0.19 \pm 0.01	0.086 \pm 0.005
P17	0.126 \pm 0.005	0.002 \pm 0.005	0.006 \pm 0.005	0.083 \pm 0.005	0.079 \pm 0.061
P18	0.35 \pm 0.008	0.013 \pm 0.006	0.013 \pm 0.005	0.12 \pm 0.01	0.18 \pm 0.01
P19	0.15 \pm 0.008	0.02 \pm 0.01	0.18 \pm 0.02	0.21 \pm 0.01	0.336 \pm 0.005
P20	0.09 \pm 0.008	0.02 \pm 0.01	0.013 \pm 0.005	0.186 \pm 0.006	0.187 \pm 0.006
P21	0.07 \pm 0.008	0.02 \pm 0.01	0.006 \pm 0.005	0.11 \pm 0.01	0.143 \pm 0.005
P22	0.17 \pm 0.008	0.04 \pm 0.01	0.013 \pm 0.006	0.20 \pm 0.01	0.18 \pm 0.01
P23	0.54 \pm 0.008	0.02 \pm 0.01	0.006 \pm 0.005	0.147 \pm 0.006	0.187 \pm 0.006
P24	0.176 \pm 0.013	0.013 \pm 0.006	0.013 \pm 0.006	0.133 \pm 0.006	0.123 \pm 0.006
P25	0.27 \pm 0.008	0.027 \pm 0.005	0.01 \pm 0.01	0.143 \pm 0.006	0.147 \pm 0.005
P26	0.17 \pm 0.008	0.003 \pm 0.005	0.023 \pm 0.005	0.20 \pm 0.01	0.173 \pm 0.005
P27	0.08 \pm 0.008	0.013 \pm 0.005	0.09 \pm 0.01	0.143 \pm 0.005	0.26 \pm 0.001
P28	0.013 \pm 0.005	0.013 \pm 0.005	0.013 \pm 0.005	0.19 \pm 0.01	0.236 \pm 0.005
P29	0.29 \pm 0.008	0.02 \pm 0.01	0.016 \pm 0.005	0.173 \pm 0.007	0.186 \pm 0.005
P30	0.19 \pm 0.008	0.027 \pm 0.008	0.003 \pm 0.006	0.27 \pm 0.01	0.167 \pm 0.008

Determination of Toxic Heavy Metals in Different Brands of Talcum Powder

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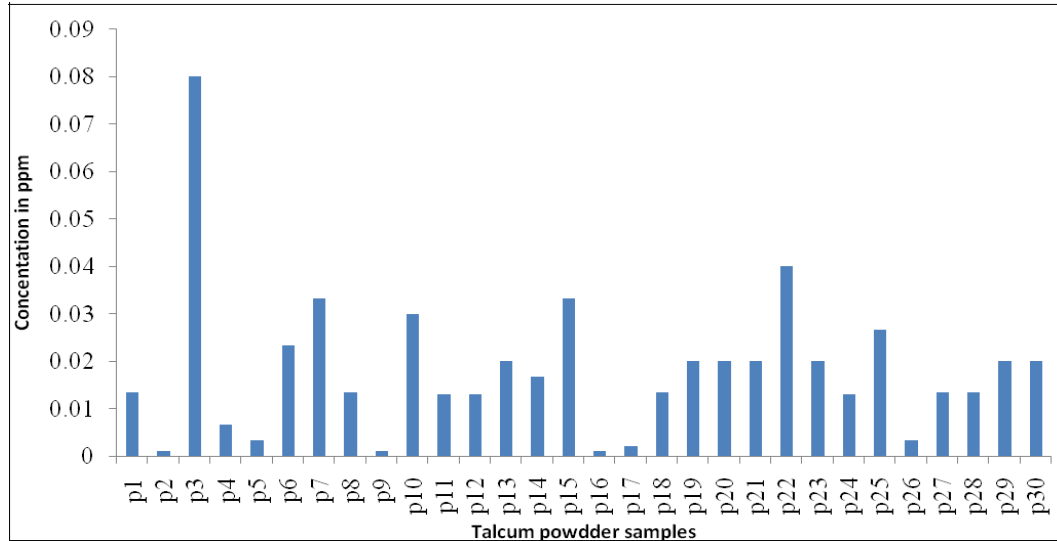


Figure 1: Concentrations of Cd in ppm 30 Different Brands of Talcum Powder Sample

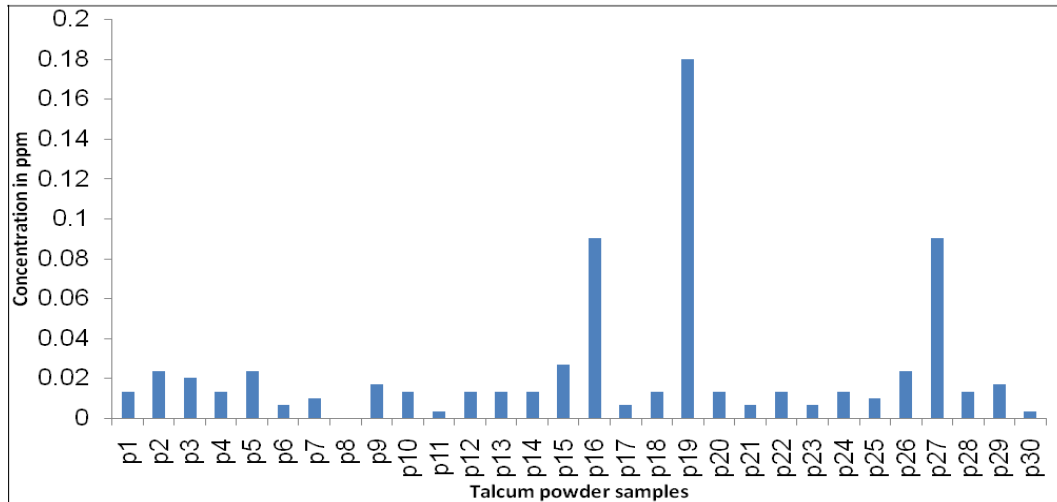


Figure 2: Concentrations of Co in ppm in 30 Different Brands of Talcum Powder Samples

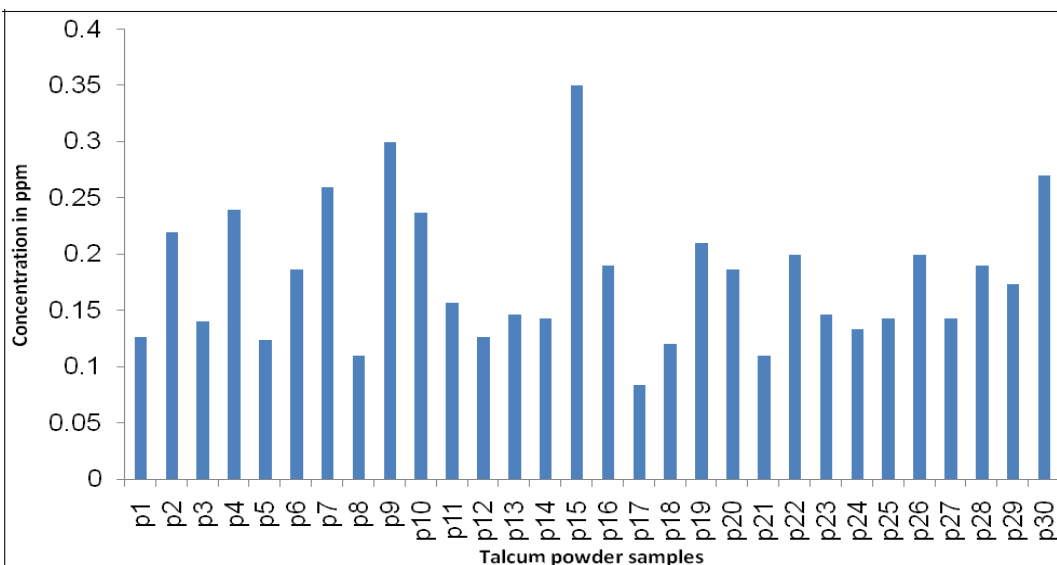


Figure 3: Concentrations of Cr in ppm 30 Different Brands of Talcum Powder Samples

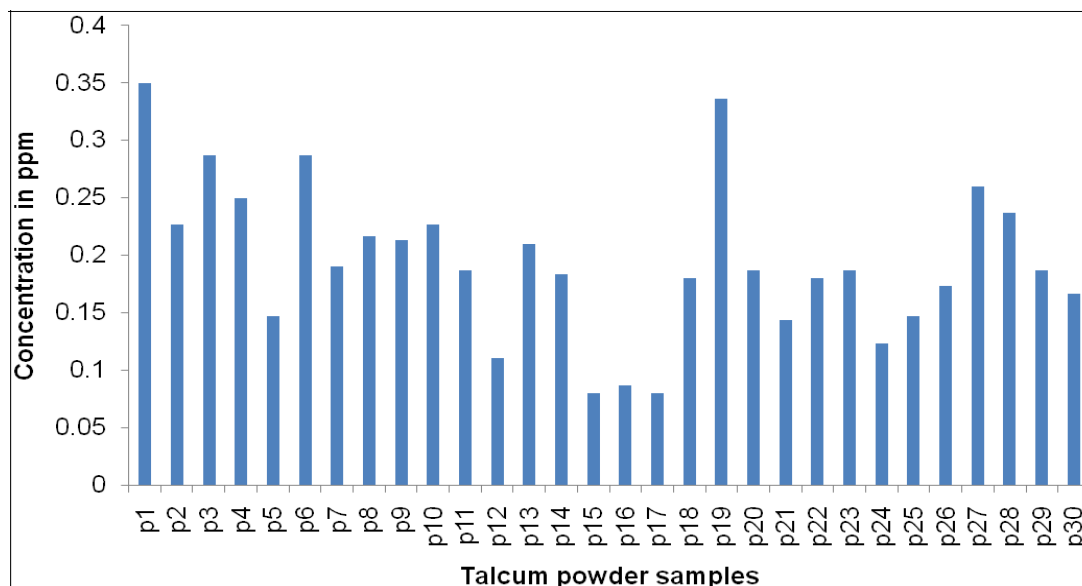


Figure 4: Concentrations of Cu in ppm 30 Different Brands of Talcum Powder Samples

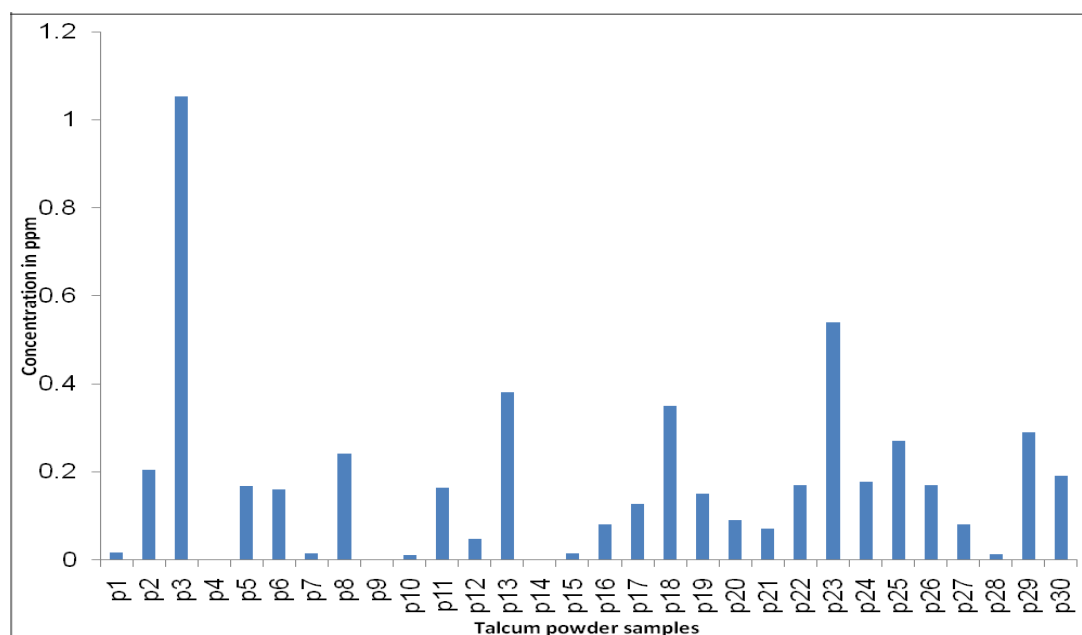


Figure 5: Concentrations of Pb in ppm in 30 Different Brands of Talcum Powder Samples

Copper is present in small amounts useful for our health but its higher amounts are dangerous for the health. The safe limit of copper is 13 ppm. Figure 4 tells that the concentration of copper is present in the range of 0.07-0.35 ppm. When it is inhaled above than the bearable limit then it causes many health problems in the body. The target organs of copper are liver, kidney and brain. It effects the functioning of these target organs.

Figure 5 tells about the concentration of lead in different brands of talcum powder. The concentration is in the range of 0.0006-1.05 ppm in all brands under study. Lead is a heavy metal present in our body in small quantity. The safe limit of lead is 20ppm by FDA. In trace amounts it is useful or many metabolic processes in the body of human being. The target organs of lead are bone, brain and kidney. Lead heavy metal effect the functioning of these organs.

CONCLUSIONS

All the metals are present in safe limits in 30 brands of talcum powder. But the excess use of talcum powder affects the health of consumer. When infants inhale the talcum powder in excess amount accidentally then the heavy metals present in it affect them.

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Exhibit 82

Molecular Basis Supporting the Association of Talcum Powder Use With Increased Risk of Ovarian Cancer

Reproductive Sciences
1-10
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Abstract

Genital use of talcum powder and its associated risk of ovarian cancer is an important controversial topic. Epithelial ovarian cancer (EOC) cells are known to manifest a persistent prooxidant state. Here we demonstrated that talc induces significant changes in key redox enzymes and enhances the prooxidant state in normal and EOC cells. Using real-time reverse transcription polymerase chain reaction and enzyme-linked immunosorbent assay, levels of CA-125, caspase-3, nitrate/nitrite, and selected key redox enzymes, including myeloperoxidase (MPO), inducible nitric oxide synthase (iNOS), superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GPX), and glutathione reductase (GSR), were determined. TaqMan genotype analysis utilizing the QuantStudio 12K Flex was used to assess single-nucleotide polymorphisms in genes corresponding to target enzymes. Cell proliferation was determined by MTT proliferation assay. In all talc-treated cells, there was a significant dose-dependent increase in prooxidant iNOS, nitrate/nitrite, and MPO with a concomitant decrease in antioxidants CAT, SOD, GSR, and GPX ($P < .05$). Remarkably, talc exposure induced specific point mutations that are known to alter the activity in some of these key enzymes. Talc exposure also resulted in a significant increase in inflammation as determined by increased tumor marker CA-125 ($P < .05$). More importantly, talc exposure significantly induced cell proliferation and decreased apoptosis in cancer cells and to a greater degree in normal cells ($P < .05$). These findings are the first to confirm the cellular effect of talc and provide a molecular mechanism to previous reports linking genital use to increased ovarian cancer risk.

Keywords

talc, epithelial ovarian cancer, oxidative stress, single-nucleotide polymorphism, cell proliferation

Introduction

Ovarian cancer is the most lethal gynecologic malignancy and ranks fifth in cancer deaths among women diagnosed with cancer.¹ Epithelial ovarian cancer (EOC) has long been considered a heterogeneous disease with respect to histopathology, molecular biology, and clinical outcome.^{1,2} Although surgical techniques and treatments have advanced over the years, the prognosis of EOC remains poor, with a 5-year survival rate of 50% in advanced stage.² This is largely due to the lack of early warning symptoms and screening methods and the development of chemoresistance.^{1,2} Moreover, ovarian cancer is known to be associated with germline mutations in the *BRCA1* or *BRCA2* genes, but with a rate of only 20 % to 40%, suggesting the presence of other unknown mutations in other predisposition genes.³ Additional genetic variations including single-nucleotide polymorphisms (SNPs) have been hypothesized to act as low to moderate penetrant alleles that contribute to ovarian cancer risk.^{3,4}

The pathophysiology of EOC is not fully understood but has been strongly associated with inflammation and the resultant

oxidative stress.⁵ We have previously characterized EOC cells to manifest a persistent prooxidant state as evident by the upregulation of key oxidants and downregulation of key antioxidants, which is further enhanced in chemoresistant EOC cells.⁶ The expression of key prooxidant/inflammatory enzymes such as inducible nitric oxide synthase (iNOS), nicotinamide adenine dinucleotide phosphate (NAD(P)H) oxidase, and myeloperoxidase (MPO), as well as an increase in nitric oxide (NO) levels, was increased in EOC tissues and cells.⁶ Additionally, we have shown that EOC cells manifest lower apoptosis, which

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was markedly induced by inhibiting iNOS, indicating a strong link between apoptosis and NO/iNOS pathways in these cells.⁶

The cellular redox balance is maintained by key antioxidants including catalase (CAT), superoxide dismutase (SOD), or by glutathione peroxidase (GPX) coupled with glutathione reductase (GSR).⁵ Other important scavengers include thioredoxin coupled with thioredoxin reductase, and glutaredoxin, which utilizes glutathione (GSH) as a substrate.⁷ We have previously reported that a genotype switch in key antioxidants is a potential mechanism leading to the acquisition of chemoresistance in EOC cells.⁷ We have studied the effects of genetic polymorphisms in key redox genes on the acquisition of the oncogenic phenotype in EOC cells, including genes that control the levels of cellular reactive oxygen species and oxidative damage and SNPs for genes involved in carcinogen metabolism (detoxification and/or activation), antioxidants, and DNA repair pathways.^{4,6} Several function-altering SNPs have been identified in key antioxidants, including CAT, GPX, GSR, and SOD.⁴

Several studies have suggested the possible association between genital use of talcum powder and risk of EOC.⁷⁻¹² Association between the use of cosmetic talc in genital hygiene and ovarian cancer was first described in 1982 by Cramer et al, and many subsequent studies supported this finding.⁷⁻¹² Talc and asbestos are both silicate minerals; the carcinogenic effects of asbestos have been extensively studied and documented in the medical literature.⁷⁻¹² Asbestos fibers in the lung initiate an inflammatory and scarring process, and it has been proposed that ground talc, as a foreign body, might initiate a similar inflammatory response.⁷ The objective of this study was to determine the effects of talcum powder on the expression of key redox enzymes, CA-125 levels, and cell proliferation and apoptosis in normal and EOC cells.

Material and Methods

Cell Lines

Ovarian cancer cells SKOV-3 (ATCC), A2780 (Sigma Aldrich, St Louis, Missouri), and TOV112D (a kind gift from Gen Sheng Wu at Wayne State University, Detroit, Michigan) and normal cells human macrophages (EL-1; ATCC, Manassas, Virginia), human primary normal ovarian epithelial cells (Cell Biologics, Chicago, Illinois), human ovarian epithelial cells (HOSEpiC; ScienCell Research Laboratories, Inc, Carlsbad, California), and immortalized human fallopian tube secretory epithelial cells (FT33; Applied Biological Materials, Richmond, British Columbia, Canada) were used. All cells were grown in media and conditions following manufacturer's protocol. EL-1 cells were grown in IMDM media (ATCC) supplemented with 0.1 mM hypoxanthine and 0.1 mM thymidine solution (H-T, ATCC) and 0.05 mM β -mercaptoethanol. SKOV-3 EOC cells were grown in HyClone McCoy's 5A medium (Fisher Scientific, Waltham, Massachusetts), A2780 EOC cells were grown in HyClone RPMI-1640 (Fisher Scientific), and both TOV112D EOC cells were grown in MCDB105

(Cell Applications, San Diego, California) and Medium 199 (Fisher Scientific; 1:1). All media were supplemented with fetal bovine serum (Innovative Research, Novi, Michigan) and penicillin/streptomycin (Fisher Scientific), per their manufacturer specifications. Human primary normal ovarian epithelial cells were grown in complete human epithelial cell medium (Cell Biologics).

Treatment of Cells

Talcum baby powder (Johnson & Johnson, New Brunswick, NJ, #30027477, Lot#13717RA) was dissolved in dimethyl sulfoxide (DMSO; Sigma Aldrich) at a concentration of 500 mg in 10 mL and was filtered with a 0.2 μ m syringe filter (Corning). Sterile DMSO was used as a control for all treatments. Cells were seeded in 100-mm cell culture dishes (3×10^6) and were treated 24 hours later with 5, 20, or 100 μ g/mL of talc for 72 hours. Cell pellets were collected for RNA, DNA, and protein extraction. Cell culture media were collected for CA-125 analysis by enzyme-linked immunosorbent assay (ELISA).

Real-Time Reverse Transcription Polymerase Chain Reaction

Total RNA was extracted from all cells using the RNeasy mini kit (Qiagen, Valencia, California). Measurement of the amount of RNA in each sample was performed using a Nanodrop spectrophotometer (Thermo Fisher Scientific, Waltham, Massachusetts). A 20 μ L complementary DNA reaction volume containing 0.5 μ g RNA was prepared using the SuperScript VILO Master Mix Kit (Life Technologies, Carlsbad, California). Optimal oligonucleotide primer pairs were selected for each target using Beacon designer (Premier Biosoft, Inc; Table 1). Quantitative reverse transcription polymerase chain reaction (RT-PCR) was performed using the EXPRESS SYBR GreenER qPCR supermix kit (Life Technologies) and the Cepheid 1.2f detection system (Sunnyvale, CA) previously described.⁶ Standards with known concentrations and lengths were designed specifically for β -actin (79 bp), CAT (105 bp), NOS2 (89 bp), GSR (103 bp), GPX1 (100 bp), MPO (79 bp), and SOD3 (84 bp), allowing for construction of a standard curve using a 10-fold dilution series.⁶ All samples were normalized to β -actin. A final melting curve analysis was performed to demonstrate specificity of the PCR product.

Protein Detection

Cell pellets were lysed utilizing cell lysis buffer (20 mM Tris-HCl [pH 7.5], 150 mM NaCl, 1 mM Na₂EDTA, 1 mM EGTA, 1% Triton, 2.5 sodium pyrophosphate, 1 mM β -glycerophosphate, 1 mM Na₃VO₄, 1 μ g/mL leupeptin) containing a cocktail of protease inhibitors. Samples were centrifuged at 13 000 rpm for 10 minutes at 4 C. Total protein concentration of cell lysates from control and talc-treated cells was measured with the Pierce BCA protein assay kit (Thermo Scientific, Rockford, Illinois).

Table 1. Real-Time RT-PCR Oligonucleotide Primers.

Accession Number	Gene	Sense (5'-3')	Antisense (3'-5')	Amplicon (bp)	Annealing Time (seconds) and Temperature (°C)
NM_001101	<i>β-actin</i>	ATGACTTAGTTGCGTTACAC	AATAAAGCCATGCCAATCTC	79	10, 64
NM_001752	<i>CAT</i>	GGTTGAACAGATAGCCTTC	CGGTGAGTGTGAGGATAG	105	10, 63
NM_003102	<i>SOD3</i>	GTGTTCTGCTGCTCCT	TCCGCCGAGTCAGAGTTG	84	60, 64
NM_000637	<i>GSR</i>	TCACCAAGTCCCATATAGAAATC	TGTGGCGATCAGGATGTG	116	10, 63
NM_000581	<i>GPX1</i>	GGACTACACCCAGATGAAC	GAGCCCTTGCGAGGTGTAG	91	10, 66
NM_000625	<i>NOS2</i>	GAGGACCACATCTACCAAGGAGGAG	CCAGGCAGGCGGAATAGG	89	30, 59
NM_000250	<i>MPO</i>	CACTTGTATCCTCTGGTTCTTCAT	TCTATATGCTTCTCACGCCTAGTA	79	60, 63

Abbreviation: RT-PCR, reverse transcription polymerase chain reaction.

Detection of Protein/Activity by ELISA

The following ELISA kits were used (Cayman Chemical, Ann Arbor, Michigan): CAT, SOD, GSR, GPX, and MPO. Nitrite (NO_2^-)/nitrate (NO_3^-) were determined spectrophotometrically by Griess assay as previously reported.⁶ CA-125 protein levels were measured in cell media by ELISA (Ray Biotech, Norcross, Georgia).

TaqMan SNP Genotyping Assay

DNA was isolated utilizing the EZ1 DNA tissue kit (Qiagen) for EOC cells. The TaqMan SNP genotyping assay set (Applied Biosystems, Carlsbad, California; NCBI dbSNP genome build 37, MAF source 1000 genomes) was used to genotype the SNPs (Table 1). The Applied Genomics Technology Center (AGTC, Wayne State University) performed these assays. Analysis was done utilizing the QuantStudio 12 K Flex real-time PCR system (Applied Biosystems).

Cell Proliferation and Apoptosis

Cell proliferation was assessed with the TACS MTT cell proliferation assay (Trevigen, Gaithersburg, Maryland) after treatment with talc (100 $\mu\text{g/mL}$) for 24 hours. The Caspase-3 Colorimetric Activity Assay Kit (Chemicon, Temecula, California) was used to determine levels of caspase-3 activity after treatment of normal and EOC cells with various doses of talc as previously described.⁶ Equal concentrations of cell lysate were used. The assay is based on spectrophotometric detection of the chromophore p-nitroaniline (pNA) after cleavage from the labeled substrate DEVD-pNA. The free pNA can be quantified using a spectrophotometer or a microtiter plate reader at 405 nm. Comparison of the absorbance of pNA from an apoptotic sample with its control allows determination of the percentage increase in caspase-3 activity.

Statistical Analysis

Normality was examined using the Kolmogorov-Smirnov test and by visual inspection of quantile-quantile plots. Because most of the data were not normally distributed, differences in distributions were examined using the Kruskal-Wallis test.

Generalized linear models were fit to examine pairwise differences in estimated least squares mean expression values by exposure to 0, 5, 20, or 100 $\mu\text{g/mL}$ of talc. We used the Tukey-Kramer adjustment for multiple comparisons, and the regression models were fit using log2 transformed analyte expression values after adding a numeric constant “1” to meet model assumptions while avoiding negative transformed values. *P* values below .05 are statistically significant.

Results

Talc Treatment Decreased the Expression of Antioxidant Enzymes SOD and CAT in Normal and EOC Cells

Real-time RT-PCR and ELISA assays were utilized to determine the CAT and SOD messenger RNA (mRNA) and protein levels in cells before and after 72 hours talc treatment, respectively (Figure 1). The CAT (Figure 1A and C) and SOD (Figure 1B and D) mRNA and protein levels were significantly decreased in a dose-dependent manner in talc-treated cells compared to controls ($P < .05$).

Talc Treatment Increased the Expression of Prooxidants iNOS, NO_2^- / NO_3^- , and MPO in Normal and EOC Cells

Real-time RT-PCR and NO_2^- / NO_3^- assays were utilized to determine the iNOS mRNA and NO levels in cells before and after 72 hours talc treatment, respectively (Figure 2). The iNOS mRNA and NO levels were significantly increased in a dose-dependent manner in talc-treated cells as compared to their controls (Figure 2A and C, $P < .05$). As expected, there was no detectable MPO in normal ovarian and fallopian tube cells, and thus, talc treatment did not have any effect. However, MPO mRNA and protein levels were significantly increased in a dose-dependent manner in talc-treated ovarian cancer cells and macrophages compared to controls (Figure 2B and D, $P < .05$).

Talc Treatment Decreased the Expression of Antioxidant Enzymes, GPX and GSR, in Normal and EOC Cells

Real-time RT-PCR and ELISA assays were utilized to determine the GPX and GSR mRNA and protein levels in cells before and

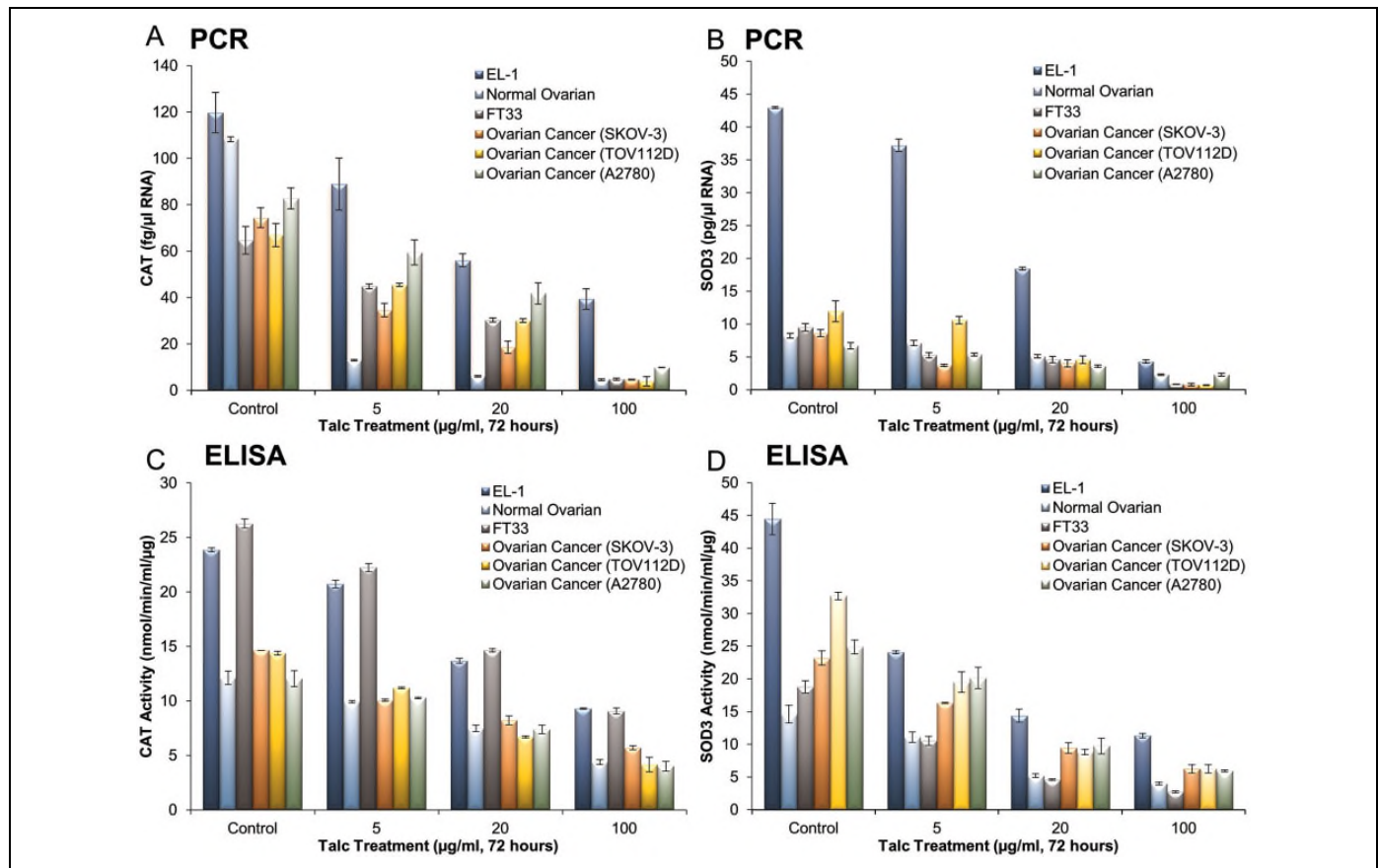


Figure 1. Decreased expression and activity of key antioxidant enzymes, CAT and SOD3. The mRNA (real-time RT-PCR) and protein/activity levels (ELISA) of CAT (A and C) and SOD3 (B and D) were determined in macrophages (EL-1), human primary ovarian epithelial cells (normal ovarian), fallopian tube (FT33), and ovarian cancer (SKOV-3, TOV112D, and A2780) cell lines before and after treatment with various doses of talc over 72 hours. Experiments were performed in triplicate. Expression is depicted as the mean, with error bars representing standard deviation. All changes in response to talc treatment were significant ($P < .05$) in all cells and in all doses as compared to controls. CAT indicates catalase; SOD3, superoxide dismutase 3; mRNA, messenger RNA; RT-PCR, reverse transcription polymerase chain reaction; ELISA, enzyme-linked immunosorbent assay.

after 72 hours of talc treatment, respectively (Figure 3). The GPX (Figure 3A and C) and GSR (Figure 3B and D) mRNA and protein levels were significantly decreased in a dose-dependent manner in talc-treated cells compared to controls ($P < .05$).

Talc Exposure Induced Known Genotype Switches in Key Oxidant and Antioxidant Enzymes

Talc treatment was associated with a genotype switch in *NOS2* from the common C/C genotype in untreated cells to T/T, the SNP genotype, in talc-treated cells, except in A2780 and TOV112D (Table 2). Additionally, the observed decrease in CAT expression and activity was associated with a genotype switch from common C/C genotype in CAT in untreated cells to C/T, the SNP genotype, in TOV112D and all normal talc-treated cells. However, there was no detectable genotype switch in CAT in A2780, SKOV3, and TOV112D (Table 2). Remarkably, there was no observed genotype switch in the selected SNP for SOD3 and GSR in all talc-treated cells. All cells, except for HOSEpiC cells, manifest the SNP genotype of

GPX1 (C/T). Intriguingly, talc treatment reversed this SNP genotype to the normal genotype (Table 2).

Talc Treatment Increased CA-125 Levels in Normal and EOC Cells

CA-125 ELISA assay was performed in protein isolated from cell media before and after talc treatment. CA-125 levels were significantly increased in a dose-dependent manner in all cells (Figure 4, $P < .05$). There was no detectable CA-125 protein in macrophages.

Talc Treatment Increased Cell Proliferation and Decreased Apoptosis

MTT cell proliferation assay was used to determine cell viability, and caspase-3 activity assay was utilized to determine apoptosis of all cell lines after 24 hours of talc treatment (Figure 5). Cell proliferation was significantly increased from the baseline in all talc-treated cells ($P < .05$), but to a greater degree in normal

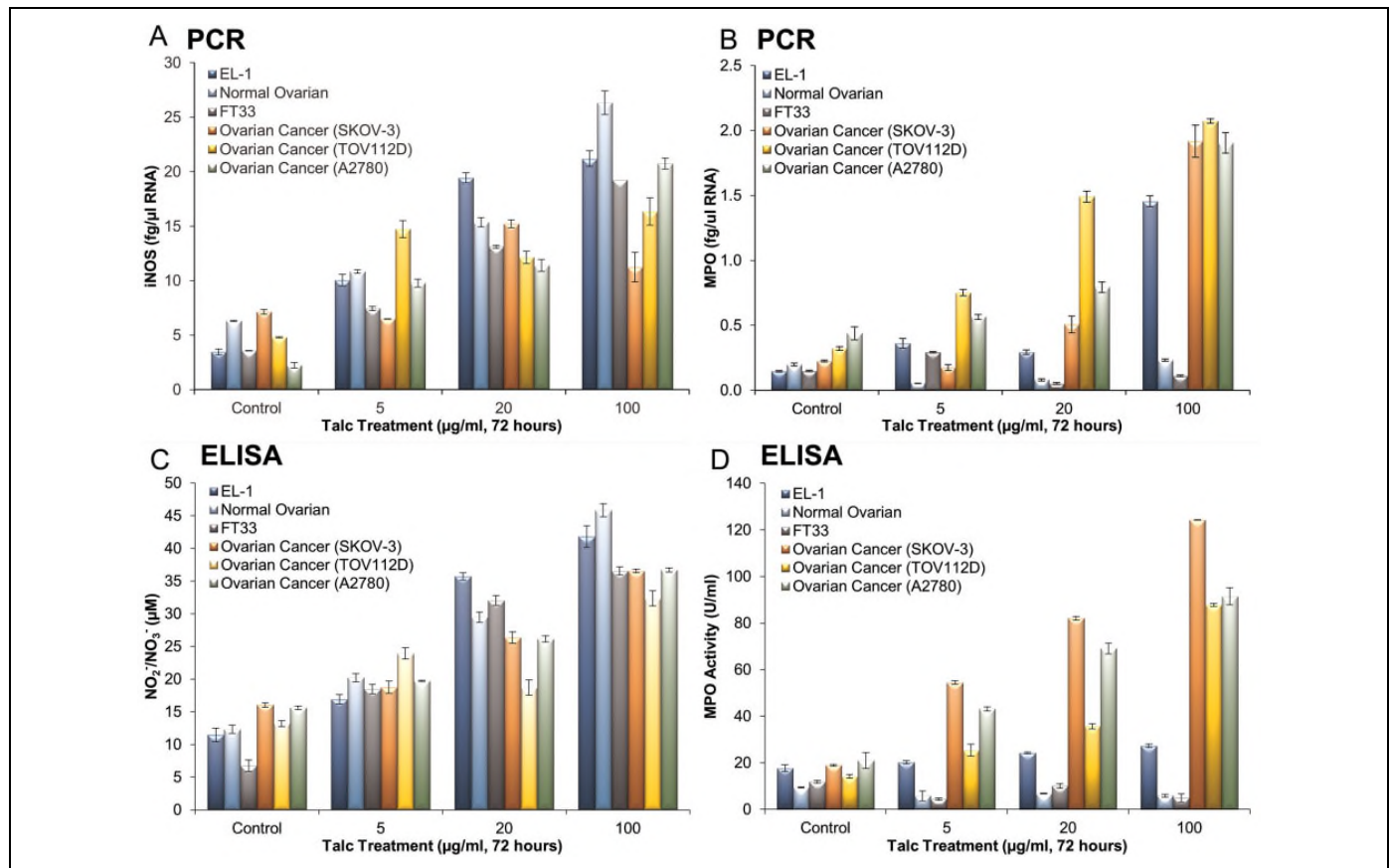


Figure 2. Increased expression and activity of key prooxidants, iNOS, $\text{NO}_2^-/\text{NO}_3^-$, and MPO. The mRNA (real-time RT-PCR) and protein/activity levels (ELISA) of iNOS (A and C) and MPO (B and D) were determined in macrophages (EL-1), human primary ovarian epithelial cells (normal ovarian), fallopian tube (FT33), and ovarian cancer (SKOV-3, TOV112D, and A2780) cell lines before and after treatment with various doses of talc over 72 hours. As expected, there was no detectable MPO in normal ovarian and fallopian tube cells, and thus, talc treatment did not have any effect. Experiments were performed in triplicate. Expression is depicted as the mean, with error bars representing standard deviation. All changes in response to talc treatment were significant ($P < .05$) in iNOS and MPO-positive cells and in all doses as compared to controls. iNOS indicates inducible nitric oxide synthase; MPO, myeloperoxidase; mRNA, messenger RNA; RT-PCR, reverse transcription polymerase chain reaction; ELISA, enzyme-linked immunosorbent assay.

as compared to cancer cells. As anticipated, caspase-3 was significantly reduced in cancer as compared to normal cells. Talc treatment resulted in decreased caspase-3 activity in all cells as compared to controls (Figure 6, $P < .05$), indicating a decrease in apoptosis.

Discussion

The claim that regular use of talcum powder for hygiene purpose is associated with an increased risk of ovarian cancer is based on several reports confirming the presence of talc particles in the ovaries and other parts of the female reproductive tract as well as in lymphatic vessels and tissues of the pelvis.⁷⁻¹² The ability of talc particles to migrate through the genital tract to the distal fallopian tube and ovaries is well accepted.¹⁰ To date, the exact mechanism is not fully understood, though several studies have pointed toward the peristaltic pump feature of the uterus and fallopian tubes, which is known to enhance transport of sperm into the oviduct ipsilateral to the ovary bearing the dominant follicle.⁸⁻¹²

There are reports supporting the epidemiologic association of talc use and risk of ovarian cancer.^{11,12} Recent studies have shown that risks for EOC from genital talc use vary by histologic subtype, menopausal status at diagnosis, hormone therapy use, weight, and smoking. These observations suggest that estrogen and/or prolactin may play a role via macrophage activity and inflammatory response to talc. There has been debate as to the significance of the epidemiologic studies based on the fact that the reported epidemiologic risk of talc use and risk of ovarian cancer, although consistent, are relatively modest (30%-40%), and there is inconsistent increase in risk with duration of use. This observation is due, in part, to the challenges in quantifying exposure as well as the failure of epidemiological studies to obtain necessary information about the frequency and duration of usage.¹¹⁻¹³

In this study, we have shown beyond doubt that talc alters key redox and inflammatory markers, enhances cell proliferation, and inhibits apoptosis, which are hallmarks of ovarian cancer. More importantly, this effect is also manifested by talc in normal cells, including surface ovarian epithelium,

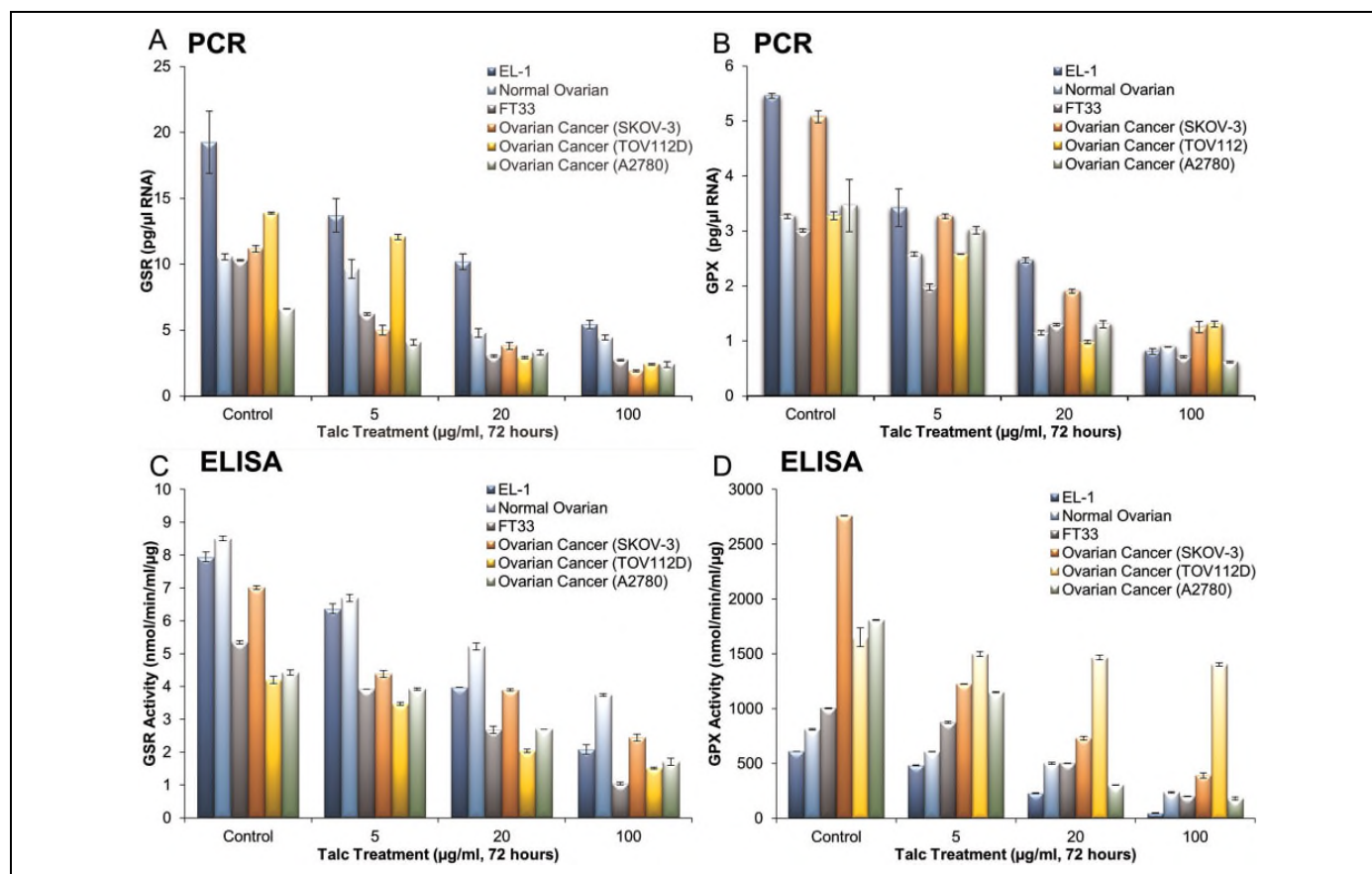


Figure 3. Decreased expression and activity of key antioxidant enzymes, GSR and GPX. The mRNA (real-time RT-PCR) and protein/activity levels (ELISA) of GSR (A and C) and GPX (B and D) were determined in macrophages (EL-1), human primary ovarian epithelial cells (normal ovarian), fallopian tube (FT33), and ovarian cancer (SKOV-3, TOV112D, and A2780) cell lines before and after treatment with various doses of talc over 72 hours. Experiments were performed in triplicate. Expression is depicted as the mean, with error bars representing standard deviation. All changes in response to talc treatment were significant ($P < .05$) in all cells and in all doses as compared to controls. GSR indicates glutathione reductase; GPX, glutathione peroxidase; mRNA, messenger RNA; RT-PCR, reverse transcription polymerase chain reaction; ELISA, enzyme-linked immunosorbent assay.

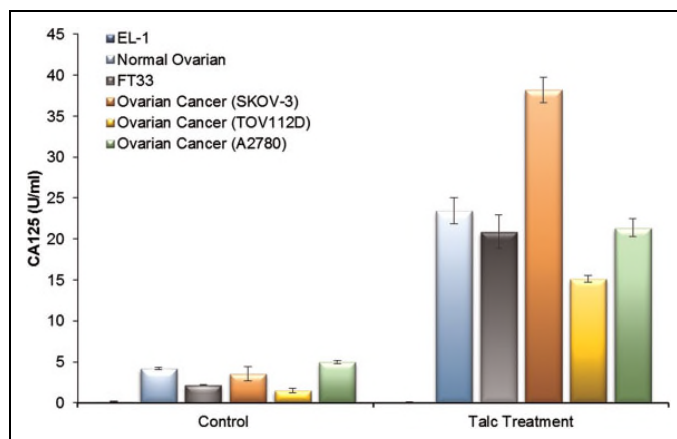
fallopian tube, and macrophages. Oxidative stress has been implicated in the pathogenesis of ovarian cancer, specifically by increased expression of several key prooxidant enzymes such as iNOS, MPO, and NAD(P)H oxidase in EOC tissues and cells as compared to normal cells indicating an enhanced redox state, as we have recently demonstrated (Figure 7).⁶ This redox state is further enhanced in chemoresistant EOC cells as evident by a further increase in iNOS and $\text{NO}_2^-/\text{NO}_3^-$ and a decrease in GSR levels, suggesting a shift toward a prooxidant state.⁶ Antioxidant enzymes, key regulators of cellular redox balance, are differentially expressed in various cancers, including ovarian.^{6,14} Specifically, GPX expression is reduced in prostate, bladder, kidney, and estrogen receptor negative breast cancer cell lines, though GPX is increased in other cancerous tissues from breast.¹⁴ Glutathione reductase levels, on the other hand, are elevated in lung cancer, although differentially expressed in breast and kidney cancer.^{5,15} Similarly, CAT was decreased in breast, bladder, and lung cancer while increased in brain cancer.¹⁶⁻¹⁸ Superoxide dismutase is expressed in lung, colorectal, gastric ovarian, and breast

cancer, while decreased activity and expression have been reported in colorectal carcinomas and pancreatic cancer cells.¹⁸⁻²¹ Collectively, this differential expression of antioxidants demonstrates the unique and complex redox microenvironment in cancer. Glutathione reductase is a flavoprotein that catalyzes the NADPH-dependent reduction of oxidized glutathione (GSSG) to GSH. This enzyme is essential for the GSH redox cycle that maintains adequate levels of reduced cellular GSH. A high GSH to GSSG ratio is essential for protection against oxidative stress (Figure 5). Treatment with talc significantly reduced GSR in normal and cancer cells, altering the redox balance (Figure 3A and C). Likewise, GPX is an enzyme that detoxifies reactive electrophilic intermediates and thus plays an important role in protecting cells from cytotoxic and carcinogenic agents. Overexpression of GPX is triggered by exogenous chemical agents and reactive oxygen species and is thus thought to represent an adaptive response to stress.¹⁵ Indeed, treatment of normal and cancer cells with talc significantly reduced GPX, which compromised the overall cell response to stress (Figure 3B and D).

Table 2. SNP Characteristics (A) and SNP Genotyping of Key Redox Enzymes in Untreated and Talc-Treated (100 µg/mL) Human Primary Ovarian Epithelial Cells (Normal Ovarian), Human Ovarian Surface Epithelial Cells (HOSEpiC), Fallopian Tube (FT33), and Ovarian Cancer (A2780, SKOV-3, TOV112D) Cell Lines (B).

	Gene (rs Number)				
	CAT (rs769217)	NOS ₂ (rs2297518)	GSR (rs8190955)	GPX1 (rs3448)	SOD3 (rs2536512)
A					
MAF	0.123	0.173	0.191	0.176	0.476
SNP	C-262T	C2087T	G201T	C-1040T	A377T
Chromosome location	11p13	17q11.2	8p12	3q21.31	4p15.2
Amino acid switch	Isoleucine to Threonine	Serine to Leucine	Unknown	Unknown	Alanine to threonine
Effect on activity	Decrease	Increase	Unknown	Unknown	Decrease
B					
A2780: Control	C/C	C/C	G/G	C/T	A/A
A2780: Talc	C/C	C/C	G/G	C/C	A/A
SKOV-3: Control	C/C	C/C	G/G	C/T	A/A
SKOV-3: Talc	C/C	T/T	G/G	C/C	A/A
TOV112D: Control	C/C	C/C	G/G	C/T	A/A
TOV112D: Talc	C/T	C/C	G/G	C/C	A/A
HOSEpiC: Control	C/C	C/C	G/G	C/T	A/A
HOSEpiC: Talc	C/T	T/T	G/G	C/T	A/A
FT33: Control	C/C	C/C	G/G	C/T	A/A
FT33: Talc	C/T	T/T	G/G	C/C	A/A
Normal ovarian: Control	C/C	C/C	G/G	C/T	A/A
Normal ovarian: Talc	C/T	T/T	G/G	C/C	A/A

Abbreviation: SNP, single-nucleotide polymorphism.

**Figure 4.** Increased CA-125 levels in response to talc treatment. The level of ovarian cancer biomarker CA-125 was determined by ELISA before and after 72 hours of talc treatment (100 µg/mL) in macrophages (EL-1), human primary ovarian epithelial cells (normal ovarian), fallopian tube (FT33), and ovarian cancer (SKOV-3, TOV112D, and A2780) cells. Experiments were performed in triplicate. Expression is depicted as the mean, with error bars representing standard deviation. All changes in response to talc treatment were significant ($P < .05$) in all cells as compared to controls. ELISA indicates enzyme-linked immunosorbent assay.

We have previously reported that EOC cells manifest increased cell proliferations and decreased apoptosis.⁶ In this study, we have shown that talc enhances cell proliferation and induces an inhibition in apoptosis in EOC cells, but more importantly in normal cells, suggesting talc is a stimulus to the development of the oncogenic phenotype. We also previously

reported a cross talk between iNOS and MPO in ovarian cancer, which contributed to the lower apoptosis observed in ovarian cancer cells.^{6,22} Myeloperoxidase, an abundant hemoprotein, previously known to be present solely in neutrophils and monocytes, is a key oxidant enzyme that utilizes NO produced by iNOS as a 1-electron substrate generating NO⁺, a labile nitrosylating species.^{6,23,24} We were the first to report that MPO was expressed by EOC cells and tissues and that silencing MPO gene expression utilizing MPO-specific siRNA induced apoptosis in EOC cells through a mechanism that involved the S-nitrosylation of caspase-3 by MPO.²² Additionally, we have compelling evidence that MPO serves as a source of free iron under oxidative stress, where both NO⁺ and superoxide are elevated.⁶ Iron reacts with hydrogen peroxide (H₂O₂) and catalyzes the generation of highly reactive hydroxy radical (HO[•]), thereby increasing oxidative stress, which in turn increases free iron concentrations by the Fenton and Haber-Weiss reaction.^{6,24} We have previously highlighted the potential benefits of the combination of serum MPO and free iron as biomarkers for early detection and prognosis of ovarian cancer.²⁵ Collectively, we now have substantial evidence demonstrating that altered oxidative stress may play a role in maintaining the oncogenic phenotype of EOC cells. Treatment of normal or ovarian cancer cells with talc resulted in a significant increase in MPO and iNOS, supporting the role of talc in the enhancement of a prooxidant state that is a major cause in the development and maintenance of the oncogenic phenotype (Figure 2).

Furthermore, CA-125, which exists as a membrane-bound and secreted protein in EOC cells, has been established as a

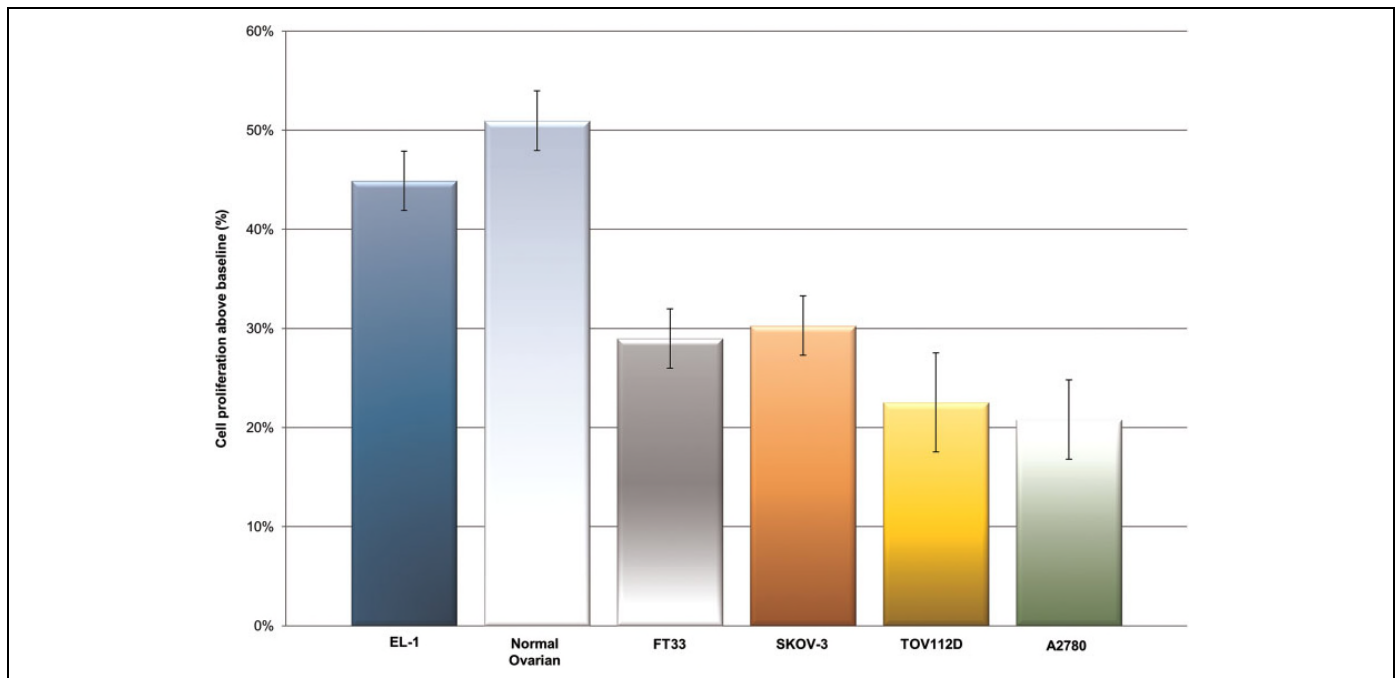


Figure 5. Increased cell proliferation in response to talc treatment. Cell proliferation was determined by MTT cell proliferation assay after 24 hours of talc treatment (100 µg/mL) in macrophages (EL-1), human primary ovarian epithelial cells (normal ovarian), fallopian tube (FT33), and ovarian cancer (SKOV-3, TOV112D, and A2780) cells. Experiments were performed in triplicate. Cell proliferation is depicted as the mean, with error bars representing standard deviation. All changes in response to talc treatment were significant ($P < .05$) in all cells as compared to controls.

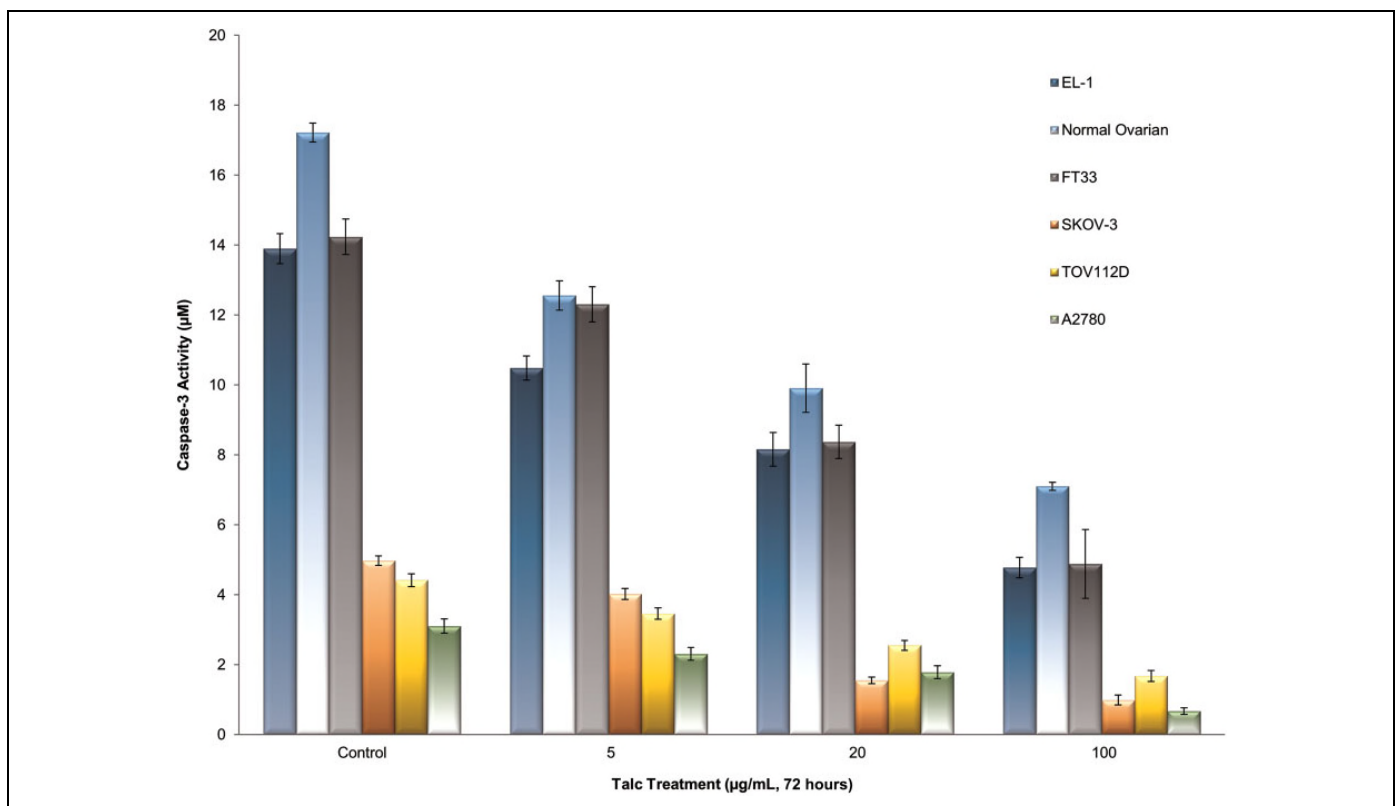


Figure 6. Decreased apoptosis in response to talc treatment. Caspase-3 activity was used to measure the degree of apoptosis in all cells. Caspase-3 activity assay was utilized to determine caspase-3 activity in macrophages (EL-1), human primary ovarian epithelial cells (normal ovarian), fallopian tube (FT33), and ovarian cancer (SKOV-3, TOV112D, and A2780) cell lines before and after treatment with various doses of talc over 72 hours. Experiments were performed in triplicate. Expression is depicted as the mean, with error bars representing standard error. All changes in response to talc treatment were significant ($P < .05$) in all cells and in all doses as compared to controls.

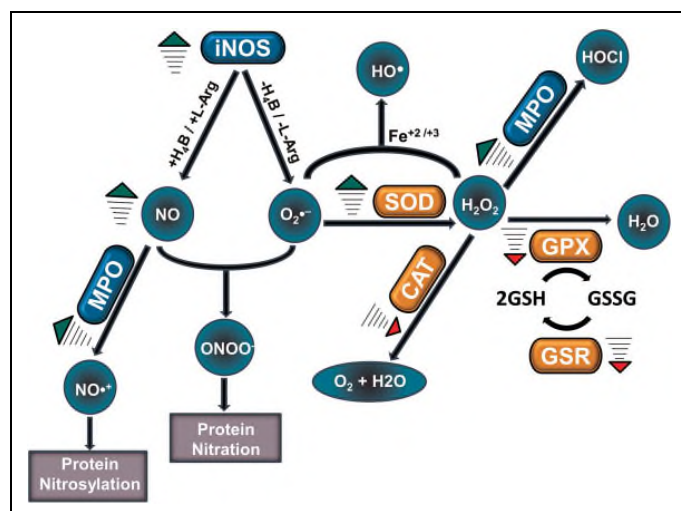


Figure 7. Epithelial ovarian cancer (EOC) cells have been reported to manifest a persistent prooxidant state as evident by the upregulation (green arrows) of key oxidants iNOS, NO, NO⁺, ONOO⁻, OH[·], O₂^{·-}, and MPO (blue) and downregulation (red arrows) of key antioxidants SOD, CAT, GPX, and GSR (orange). This redox state was also shown to be further enhanced in chemoresistant EOC cells. In this study, talcum powder altered the redox state, as indicated by the arrows, of both normal and EOC cells to create an enhanced prooxidant state. iNOS indicates inducible nitric oxide synthase; MPO, myeloperoxidase; SOD, superoxide dismutase; CAT, catalase; GPX, glutathione peroxidase; GSR, glutathione reductase.

biomarker for disease progression and response to treatment.² CA-125 expression was significantly increased from nearly undetectable levels in controls to values approaching clinical significance (35 U/mL in postmenopausal women²⁶) in talc-treated cells (Figure 4, $P < .05$) without the physiologic effects on the tumor microenvironment one would expect to be present in the human body, thus highlighting the implications of the prooxidant states caused by talc alone.

To elucidate the mechanism by which talc alters the redox balance to favor a prooxidant state not only in ovarian cancer cells, but more importantly in normal cells, we have examined selected known gene mutations corresponding to SNPs known to be associated with altered enzymatic activity and increased cancer risk.^{6,27} Our results show that the *CAT* SNP (rs769217) resulting in decreased enzymatic activity was induced in all normal cell lines tested and in TOV112D EOC lines, but was not detected in A2780 or SKOV-3 cell lines (Table 2). Nevertheless, our results confirm a decrease in *CAT* expression and enzymatic activity in all talc-treated cells (Figure 1), indicating the existence of other *CAT* SNPs. The *SOD3* (rs2536512) and *GSR* (rs8190955) SNP genotypes were not detected in any cell line, yet *SOD3* and *GSR* activity and expression were decreased in all talc-treated cells, again suggesting the presence of other SNPs. Our results have also shown that all cells, except for HOSEpiC cells, manifest the SNP genotype of *GPX1* (C/T) before talc treatment. Intriguingly, talc treatment reversed this SNP genotype to the normal genotype (Table 2). Consistent with this finding, we have previously reported that acquisition

of chemoresistance by ovarian cancer cells is associated with a switch from the *GPX1* SNP genotype to the normal *GPX1* genotype.⁶ It is not understood why a *GPX1* SNP genotype predominates in untreated normal and ovarian cancer cells. Our results showed that talc treatment was associated with a genotype switch from common C/C genotype in *NOS2* in untreated cells to T/T, the SNP genotype, in talc-treated cells, except in A2780 and TOV112D (Table 2). Nevertheless, our results confirm an increase in iNOS expression and enzymatic activity in all talc-treated cells (Figure 2), again suggesting the existence of other *NOS2* SNPs. Collectively, these findings support the notion that talc treatment induced gene point mutations that happen to correspond to SNPs in locations with functional effects, thus altering overall redox balance for the initiation and development of ovarian cancer. Future studies examining such SNPs are important to fully elucidate a genotype switch mechanism induced by talc exposure.

In summary, this is the first study to clearly demonstrate that talc induces inflammation and alters the redox balance favoring a prooxidant state in normal and EOC cells. We have shown a dose-dependent significant increase in key prooxidants, iNOS, NO₂/NO₃, and MPO, and a concomitant decrease in key antioxidant enzymes, CAT, SOD, GPX, and GSR, in all talc-treated cells (both normal and ovarian cancer) compared to their controls. Additionally, there was a significant increase in CA-125 levels in all the talc-treated cells compared to their controls, except in macrophages. The mechanism by which talc alters the cellular redox and inflammatory balance involves the induction of specific mutations in key oxidant and antioxidant enzymes that correlate with alterations in their activities. The fact that these mutations happen to correspond to known SNPs of these enzymes indicate a genetic predisposition to developing ovarian cancer with genital talcum powder use.

Authors' Note

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Saed has served as a paid consultant and expert witness in the talcum powder litigation.

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Exhibit 83



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Who Is at Risk?

Ovarian cancer is a rare disease, with carcinomas comprising approximately 90% of tumors and germ cell and stromal tumors accounting for the remainder. Ovarian carcinoma is a disease that predominantly affects postmenopausal women. Ovarian carcinomas consist of several histopathologic types, with high-grade serous being both the most common and most lethal. The category of ovarian borderline tumor or tumor of low-malignant potential, which historically had been considered in the context of ovarian cancer, is now generally considered a nonmalignant entity, although it has a postulated relationship with the development of some histologic subtypes of low-grade ovarian carcinomas.[1]

Risk factors for ovarian cancer include a family history of breast and/or ovarian cancer and inheritance of deleterious mutations in *BRCA1*, *BRCA2*, and selected other high-penetrance genes.[2-6] (Refer to the PDQ summary on [Genetics of Breast and Gynecologic Cancers](#) for more information.) Other risk factors for ovarian cancer include obesity, tall height, endometriosis, and the use of postmenopausal hormone therapy.[7-9]

Associations of some risk factors with ovarian cancer vary by histopathologic subtype. The association of endometriosis with ovarian cancer is stronger for nonserous subtypes, especially clear cell carcinoma and endometrioid subtypes.[10] Further, among carriers of deleterious mutations in *BRCA1* or *BRCA2*, increasing evidence suggests that many tumors previously classified as ovarian high-grade serous carcinoma may develop from malignant cells arising in the tubal epithelium (serous tubal intraepithelial carcinoma [STIC]), although these tumors continue to be referred to as *ovarian* cancers in most writings. It is hypothesized that high-grade serous carcinomas among individuals who are not carriers of mutations in *BRCA1* or *BRCA2* may also develop in the fallopian tube, but few STICs have been identified among these women in the absence of concurrent high-stage disease. Further, data suggest that the distinction of high-grade serous carcinomas from other histologic types of high-grade carcinomas, particularly endometrioid carcinomas, is not reliable. Reported rates of mucinous carcinoma diagnoses have declined dramatically, but expert pathology reviews suggest that this reflects increased recognition of metastases from occult gastrointestinal primary tumors to the ovary, rather than a true decline in rates of ovarian primary tumors.[11]

Factors associated with a decreased risk of ovarian cancer include multiparity, use of oral contraceptives, multiple pregnancies, breastfeeding, tubal ligation, and salpingectomy.[12-15] Compared with nulliparous women, the risk of ovarian cancer is reduced by 30% to 60% among parous women, with additive protection for each additional birth.[16,17]

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Overview

Note: Separate PDQ summaries on [Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Screening](#) and [Ovarian Epithelial, Fallopian Tube, and Primary Peritoneal Cancer Treatment](#) are also available.

Factors With Adequate Evidence of an Increased Risk of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

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Family history and inherited susceptibility to ovarian, fallopian tube, and primary peritoneal cancer

Based on solid evidence, women with a family history of ovarian cancer, especially in a first-degree relative, and those with an inherited predisposition to ovarian cancer, such as a *BRCA1* or *BRCA2* mutation, have an increased risk of developing ovarian cancer. (Refer to the PDQ summary on [Genetics of Breast and Gynecologic Cancers](#) for more information.)

Endometriosis

Based on fair evidence, self-reported and laparoscopically confirmed endometriosis is associated with an increased risk of ovarian cancer.[1,2] The association is stronger with nonserous histologic subtypes, specifically endometrioid and clear cell carcinomas.[2,3]

Magnitude of Effect: Modest with observed relative risks (RRs) of 1.8 to 2.4.

Study Design: Cohort and case-control studies.

Internal Validity: Good.

Consistency: Fair.

External Validity: Good.

Hormone replacement therapy

Based on fair evidence, current or recent hormone therapy is associated with a small increased risk of ovarian cancer. Risks attenuate after hormone therapy is discontinued. Risks did not differ by preparation type (estrogen only vs. combined estrogen/progestin).[4,5]

Magnitude of Effect: Modest with observed RRs of 1.20 to 1.8.

Study Design: One randomized clinical trial, cohort and case-control studies.

Internal Validity: Good.

Consistency: Fair.

External Validity: Good.

Obesity and height

Based on fair evidence, increases in height and body mass index (BMI) are associated with a modest increased risk of ovarian cancer.

Magnitude of Effect: Based on an overview analysis of 25,157 women with ovarian cancer and 81,211 women without ovarian cancer from 47 epidemiological studies, the RR of ovarian cancer per 5 cm increase in height is 1.07 (95% confidence interval [CI], 1.05–1.09). The RR of ovarian cancer per 5 kg/m² increase in BMI is 1.10 (95% CI, 1.07–1.13) among never-users of hormone therapy and 0.95 (95% CI, 0.92–0.99) among ever-users of hormone therapy.[6]

Study Design: Cohort and case-control studies.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Factors With Adequate Evidence of a Decreased Risk of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

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Oral contraceptives: benefits

Based on solid evidence, oral contraceptive use is associated with a decreased risk of developing ovarian cancer.

Magnitude of Effect: The degree of risk reduction varies by duration of oral contraceptive use and time since last use. For 1 to 4 years of oral contraceptive use, the RR reduction is 22%, and for 15 or more years of use, the RR reduction is 56%. The reduction in risk persisted for more than 30 years after use was discontinued, but the degree of reduction attenuated over time. The risk reduction per 5 years of oral contraceptive use was 29% for women who discontinued use less than 10 years ago and decreased to 15% for women who discontinued use 20 to 29 years ago. Ten years of use reduced cancer incidence before age 75 years from 1.2 to 0.8 per 100 users and reduced mortality from 0.7 to 0.5 per 100 users. The number needed-to-treat for 5 years was estimated to be about 185 women.

Study Design: Multiple case-control and cohort studies; meta-analyses.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Oral contraceptives: harms

Based on solid evidence, combined current use of estrogen-progestin oral contraceptive use is associated with an increased risk of venous thromboembolism, particularly among smokers, for whom use is contraindicated. Oral contraceptives are not associated with a long-term increased risk of breast cancer but may be associated with a short-term increased risk while a woman is taking oral contraceptives. The risk of breast cancer declines with time since last use.

Magnitude of Effect: The risks may vary by preparation. Overall, the absolute risk of venous thromboembolism is about three events per 10,000 women per year while taking oral contraceptives. The risk is modified by smoking. Breast cancer risk among long-term (>10 years) current users is estimated at one extra case per year per 100,000 women. The risk dissipates with time since last use.

Study Design: Observational studies.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Tubal ligation: benefits

Based on solid evidence, tubal ligation is associated with a decreased risk of ovarian cancer.

Magnitude of Effect: Adjusting for other forms of contraception, tubal ligation provides a relative reduction in the odds of developing ovarian cancer of about 30%.

Study Design: Multiple case-control studies and cohort studies.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Tubal ligation: harms

Based on fair evidence, harms include surgical risks, including the following:[7]

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- Major morbidity including blood transfusion, reoperation, or hospital readmission (rate of 1.0 per 100 procedures).
- Minor morbidity including postoperative fever, urinary tract infections, or wound infections (rate of 6.0 per 100 procedures).

Multiparity

Based on good evidence, multiparity is associated with a decreased risk of ovarian cancer.

Magnitude of Effect: Based on good evidence from multiple observational epidemiological studies, parous women have an approximately 30% lower ovarian cancer risk than nulliparous women.[6,8,9]

Study Design: Observational epidemiologic studies.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Salpingectomy

Based on limited data, salpingectomy is associated with a decrease in risk of ovarian cancer.

Magnitude of Effect: Approximately 50% decrease for bilateral salpingectomy, less protection for unilateral salpingectomy.

Study Design: Observational epidemiologic studies from several different countries.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Breastfeeding

Based on solid evidence, breastfeeding is associated with a decreased risk of ovarian cancer.

Magnitude of Effect: 2% decrease with every month of breastfeeding.[10]

Study Design: Multiple case-control and cohort studies; meta-analysis.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Risk-reducing bilateral salpingo-oophorectomy: benefits

Based on solid evidence, risk-reducing bilateral salpingo-oophorectomy is associated with a decreased risk of ovarian cancer. Peritoneal carcinomatosis has been reported rarely following surgery. Risk-reducing surgery is generally reserved for women at high risk of developing ovarian cancer, such as women who have an inherited susceptibility to ovarian cancer.

Magnitude of Effect: 90% reduction in risk of ovarian cancer observed among women with a *BRCA1* or *BRCA2* mutation.

Study Design: Multiple case-control studies.

Internal Validity: Good.

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Consistency: Good.

External Validity: Good.

Risk-reducing bilateral salpingo-oophorectomy: harms

Based on solid evidence, prophylactic oophorectomy among women who are still menstruating at the time of surgery is associated with infertility, vasomotor symptoms, decreased sexual interest, vaginal dryness, urinary frequency, decreased bone-mineral density, and increased cardiovascular disease.

Magnitude of Effect: Reported prevalence of vasomotor symptoms varies from 41% to 61.4% among women who underwent oophorectomy before natural menopause. Women with bilateral oophorectomy who did not take hormone therapy were twice as likely to have moderate or severe hot flashes compared with women who underwent natural menopause. The RR of cardiovascular disease among women with bilateral oophorectomy and early menopause was 4.55 (95% CI, 2.56–9.01).

Study Design: Cohort and case-control studies.

Internal Validity: Good.

Consistency: Good.

External Validity: Good.

Areas of Uncertainty

Ovarian hyperstimulation for infertility treatment

Evidence is poor to determine the association between ovarian hyperstimulation and the risk of ovarian cancer. Risk of ovarian cancer may be increased among women who remain nulligravid after being treated with ovarian stimulating medications.

Magnitude of Effect: Uncertain—risk of invasive ovarian cancer may be increased among women who remain nulligravid after treatment; risk of borderline ovarian tumors may be increased among women treated with infertility drugs.

Study Design: Cohort and case-control studies; systematic review.

Internal Validity: Fair.

Consistency: Poor.

External Validity: Fair.

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Description of the Evidence

Incidence and Mortality

In 2019, it is estimated that 22,530 new cases of ovarian cancer will be diagnosed and 13,980 deaths due to ovarian cancer will occur.[1] Incidence and mortality rates are higher among whites than among blacks, but statistically significant decreases in incidence and mortality rates have been observed among both whites and blacks.[2] In 2014, the overall incidence rate for ovarian carcinoma among women aged 65 years and older was 41.9 cases per 100,000 women-years.[3] Given that the Surveillance, Epidemiology, and End Results Program does not adjust for oophorectomy or salpingectomy, racial differences in the prevalence of women who had undergone these procedures could bias racial rate comparisons. A statistically significant decrease in delayed adjusted incidence of 0.9% among whites from 1987 to 2012 and 0.2% among blacks from 1992 to 2012 was observed. A statistically significant decrease in mortality rates of 2.0% per year among whites from 2002 to 2012 and 1.3% per year among blacks from 1992 to 2012 was observed. The population lifetime risk of ovarian cancer is 1.3%; the population lifetime risk of dying from ovarian cancer is 0.97%.[2]

Histology and Pathogenesis of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

Ovarian carcinoma is a biologically and clinically heterogeneous class of tumors that includes several major subtypes: serous, mucinous, endometrioid, and clear cell. Classification of ovarian carcinomas into type I and type II tumors has been proposed. In this system, type I tumors include the following:[4]

1. Endometriosis-related subtypes, such as endometrioid, clear cell, and seromucinous.
2. Low-grade serous.
3. Mucinous and malignant Brenner tumors.

Among type I tumors, endometrioid and clear cell carcinomas are numerically predominant and most important clinically. In general, type I ovarian carcinomas present at a lower stage than type II tumors and portend a better prognosis.

Type II tumors are comprised mainly of high-grade serous carcinomas, the most common and lethal of all ovarian carcinoma subtypes. These cancers usually present with symptomatic bulky stage III or IV disease and ascites. Many, but possibly not all, high-grade serous carcinomas appear to arise from malignant *in situ* lesions in the epithelium of the fallopian tube fimbria, which spread to the ovaries secondarily, but continue to be referred to as ovarian carcinomas. Evidence for a tubal origin is based mainly on examination of risk-reducing salpingo-oophorectomy

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specimens, performed among *BRCA1/BRCA2* mutation carriers, in which incidental low-volume disease enables recognition of serous tubal intraepithelial carcinoma (STIC). However, not all women with high-grade serous carcinomas have identifiable STIC and few studies of the fallopian tubes among women who are not carriers of *BRCA1/BRCA2* mutations have been performed, suggesting that pathogenesis of these tumors is not fully known. Serous carcinomas can be further divided on the basis of molecular characteristics.[5]

The heterogeneity in the etiology and pathogenesis of different ovarian cancer subtypes and variability in the classification of tumors over time and between studies pose challenges for interpretation of etiologic data. Ovarian cancer is a rare cancer, thus sample size and power of studies to detect moderate associations by cancer subtype is limited. However, clearer subtyping of cancers may assist in improving our understanding of the etiology of ovarian malignancies in future studies.

Factors With Adequate Evidence of an Increased Risk of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

Family history and inherited susceptibility to ovarian, fallopian tube, and primary peritoneal cancer

Some women are at an increased risk because of an inherited mutation, with the magnitude of that risk dependent on the affected gene and specific mutation. Underlying ovarian cancer risk can be assessed through accurate pedigrees and/or genetic markers of risk. Because of uncertainties about cancer risks associated with certain specific gene mutations, genetic information may be difficult to interpret outside of families with a high incidence of ovarian cancer.

This summary does not address multiple genetic syndromes or women who are at high risk because of inherited genetic factors. (Refer to the PDQ summaries on [Genetics of Breast and Gynecologic Cancers](#) and [Genetics of Colorectal Cancer](#) for specific information related to ovarian cancer risk associated with multiple genetic syndromes and ovarian cancer in *BRCA1/BRCA2* mutation carriers.)

Hormone replacement therapy/hormone therapy

A meta-analysis of 52 studies (17 prospective and 35 retrospective) including 21,488 ovarian cancers found increased risks with current or recent hormone replacement use in prospective studies (relative risk [RR], 1.37; 95% confidence interval [CI], 1.29–1.46), with similar results for retrospective designs. Significant relationships were found for serous and endometrioid subtypes.[6] Recent use was strongly related to risk even among women who had used hormone replacement for less than 5 years (RR, 1.41; 95% CI, 1.32–1.50). Risk declined among women who had discontinued use, with greater effects for longer periods of cessation. Risks did not differ by preparation types (estrogen only vs. combined estrogen/progestin). Risks also did not differ by age at use.[7,8]

Obesity and height

Ovarian cancer risk increases with increasing height and weight (body mass index [BMI]).[9] The Collaborative Group on Epidemiological Studies of Ovarian Cancer compiled individual data, both published and unpublished, from 47 epidemiological studies including 12,157 women with ovarian cancer and 81,311 controls. RR increased significantly with increasing height (1.07 per 5 cm height) and with increasing BMI (1.10 per 5 kg/m²). These findings were unaffected by other factors known to be associated with ovarian cancer risk, with the exception that ever-users of hormone therapy had no increased risk with increasing BMI. Given that height, weight, and BMI are thought to be strongly correlated, separating out the individual effects can be difficult. Ovarian cancer mortality has also been shown to be increased in obese women.[10,11]

Factors With Adequate Evidence of a Decreased Risk of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

Oral contraceptives

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A collaborative analysis was performed of individual data from 23,257 women with ovarian cancer and 87,303 women without ovarian cancer from 45 studies in 21 countries.[12] The studies included 13 prospective studies, 19 population-based case-control studies, and 12 hospital-based case-control studies. Oral contraceptive use was associated with a dose-response effect by duration of use, without observed changes in risk reduction by decade of use from the 1960s to 1980s, over which time the amount of estrogen in oral contraceptives was approximately halved. No risk reduction was observed for women who used oral contraceptives for less than 1 year. The risk reduction associated with use from 1 to 4 years, 5 to 9 years, 10 to 14 years, and 15 years or more was 0.78 (99% CI, 0.73–0.893), 0.64 (99% CI, 0.59–0.69), 0.56 (99% CI, 0.50–0.62), and 0.42 (99% CI, 0.36–0.49), respectively. The observed risk reduction persisted after cessation of oral contraceptive therapy but attenuated over time since last use. The proportional reduction in risk per 5 years of use was 29% (95% CI, 23%–34%) for women who had discontinued use within the last 10 years; the reduction in risk was 15% (95% CI, 9%–21%) for women who discontinued use 20 to 29 years ago.

A meta-analysis, in which the primary analysis was restricted to 24 case-control and cohort studies published since 2000 to reflect more recent types of oral contraceptive preparations, also observed a dose-response by duration of use.[13] The risk reduction among women using oral contraceptives for more than 1 year but less than 5 years was 0.77 (95% CI, 0.66–0.89), and for women using oral contraceptives for more than 10 years, the risk reduction was 0.43 (95% CI, 0.37–0.51). The authors estimated that 185 women needed to be treated for 5 years to prevent one case of ovarian cancer. Based on an estimated lifetime risk of 1.38% and prevalence of ever-use of oral contraceptives of 83%, the authors estimated a lifetime reduction of ovarian cancer attributable to oral contraceptives of 0.54%.

(Refer to the PDQ summary on [Genetics of Breast and Gynecologic Cancers](#) for specific information related to ovarian cancer risk among *BRCA1/BRCA2* mutation carriers.)

Depot-medroxyprogesterone acetate

Limited information is available on the use of injectable progestational contraceptives (depot-medroxyprogesterone acetate [DMPA]) and the risk of ovarian cancer; studies are confounded by the use of other contraceptive methods, particularly oral contraceptives. A hospital-based study conducted in Mexico and Thailand, with 224 cases and 1,781 controls (the World Health Organization Collaborative Study of Neoplasia and Steroid Contraceptives), did not observe an association between DMPA and ovarian cancer (RR, 1.07; 95% CI, 0.6–1.8).[14] However, only 22 of the cases had ever used DMPA and nine of these had used it for 6 months or less.

A subsequent multicenter study conducted in 12 hospitals in Thailand, including 330 cases and 982 matched controls, observed a statistically significant decreased risk of ovarian cancer associated with DMPA use, controlling for oral contraceptive use and other associated factors (odds ratio [OR], 0.52; 95% CI, 0.33–0.88). A dose-response association was observed but the sample size was limited in longer-term use categories.[15]

Tubal ligation

A meta-analysis of 16 case-control studies, three retrospective studies, and two prospective cohort studies observed a decreased risk of ovarian cancer associated with tubal ligation (RR, 0.66; 95% CI, 0.60–0.73).[16] The reduced risk was observed up to 14 years after tubal ligation. A population-based case-control study of 902 cases and 1,802 controls published subsequent to the meta-analysis observed an adjusted OR of 0.62 (95% CI, 0.51–0.75) associated with a history of a tubal ligation.[17] The association was adjusted for oral contraceptive use, which was also associated with a lower risk of ovarian cancer (OR, 0.62; 95% CI, 0.47–0.85) and other risk factors.[17]

Another pooling project with primary data from 13 population-based case-control studies examined the association between tubal ligation and ovarian cancer risk and included 7,942 epithelial ovarian cancers, and 13,904 controls.[18] Overall, tubal ligation was associated with a 29% reduction in risk (OR, 0.71; 95% CI, 0.66–0.77). The observed risk reduction varied by subtype of invasive cancers and was 52% (OR, 0.48; 95% CI, 0.40–49) for endometrioid cancer; 48%

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(OR, 0.52; 95% CI, 0.40–0.67) for clear cell cancer; 32% (OR, 0.68; 95% CI, 0.52–89) for mucinous cancer; and 19% (OR, 0.81; 95% CI, 0.74–0.89) for serous cancer.

A pooled analysis from 21 prospective cohort studies examined 14 hormonal, reproductive, and lifestyle factors by histologic subtype among 5,584 invasive ovarian cancers within a total sample of 1.3 million women. Overall, tubal ligation was associated with an 18% reduction in risk (OR, 0.82; 95% CI, 0.73–0.93). The observed risk reduction varied by subtype of invasive cancer and was 40% (OR, 0.60; 95% CI, 0.41–88) for endometrioid cancer; 65% (OR, 0.35; 95% CI, 0.18–0.69) for clear cell cancer; and 9% (OR, 0.91; 95% CI, 0.79–1.06) for serous cancer. There was a nonsignificant increase in risk of 1% (OR, 1.01; 95% CI, 0.60–1.71) for mucinous cancer.[19]

Breastfeeding

A meta-analysis [20] that included five prospective studies and 30 case-control studies examined the association between breastfeeding and the risk of ovarian cancer. Any breastfeeding was associated with a decreased risk of ovarian cancer (RR, 0.76; 95% CI, 0.69–0.83). The risk of ovarian cancer decreased 8% for every 5-month increase in duration of breastfeeding (95% CI, 0.90–0.95). Another meta-analysis that included five prospective studies and 35 case-control studies found that any breastfeeding was associated with a decreased risk of ovarian cancer (RR, 0.70; 95% CI, 0.64–0.76). These results are consistent with a previous meta-analysis and further support the prior finding of a suggested association between increased duration of breastfeeding and greater levels of protection.[21] Another meta-analysis of 19 studies, including four cohort and 15 case-control studies found an overall decreased risk of ovarian cancer with an OR of 0.66 (95% CI, 0.57–0.76) and an association with duration (2% decrease per month). The benefit of breastfeeding was greatest for the first 8 to 10 months.[22]

Risk-reducing salpingo-oophorectomy

Risk-reducing surgery is an option considered by women who are at high risk of ovarian cancer, such as those with an inherited susceptibility to cancer. (Refer to the [Oral contraceptives](#) section in the PDQ summary on [Genetics of Breast and Gynecologic Cancers](#) for more information on this as a risk-reducing intervention.) Among women in the general population, opportunistic salpingectomy, oophorectomy, or salpingo-oophorectomy have been considered as possible interventions at the time of surgery for other benign indications. Salpingectomy has also been discussed as a preferred means of sterilization.[23,24]

Harms

Risks associated with benign oophorectomy (with or without salpingectomy or hysterectomy) have been analyzed in six published studies. Studies of three cohorts found that oophorectomy performed before menopause (age 45 or 50 years) was associated with increased overall mortality, likely related to cardiovascular disease. This finding was noted particularly among individuals not using hormone replacement. In the Women's Health Initiative, bilateral salpingo-oophorectomy was not associated with increased mortality. In the National Health and Nutrition Examination Survey (NHANES III), oophorectomy overall was not related to mortality, but mortality was increased among obese women younger than 40 years who did not use hormone replacement. The California Teachers Study did not find a mortality risk with oophorectomy, but only 3% of women did not use hormone replacement. Overall, data suggest that oophorectomy among younger women likely increases overall mortality and that this risk may be attenuated with hormone replacement.[25–30]

Salpingectomy

Data relating salpingectomy to risk of ovarian/tubal cancer are limited, but consistent. A meta-analysis of three studies found an OR of 0.51 (95% CI, 0.35–0.71) for risk of these cancers among women who had undergone salpingectomy, compared with women who had intact fallopian tubes.[31] These studies included a Swedish record linkage study conducted from 1973 to 2009 with a mean follow-up of 23 years, which found the following hazard ratios (HRs) for risk of ovarian cancer compared with women who had not undergone surgery:

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- For hysterectomy, the HR was 0.79 (95% CI, 0.70–0.88).
- For hysterectomy with bilateral salpingo-oophorectomy, the HR was 0.06 (95% CI, 0.03–0.12).
- For salpingectomy, the HR was 0.65 (95% CI, 0.52–0.81).
- For sterilization procedures, the HR was 0.72 (95% CI, 0.64–0.81).

Protection for bilateral salpingectomy was approximately twice that for unilateral salpingectomy.[32] This report included limited covariate data but results were similar to other smaller studies included in the meta-analysis.

Limited data based on circulating surrogate markers of ovarian reserve suggest that salpingectomy does not have an adverse effect on ovarian function.[33,34]

Factors With Inadequate Evidence of an Association Risk of Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

Dietary factors

No consistent association has been observed between a variety of dietary factors and the risk of ovarian cancer.

A systematic review and meta-analysis that included 23 case-control studies and three cohort studies found no evidence of an association between alcohol use and epithelial ovarian cancer.[35]

A case-control study of the Healthy Eating Index (HEI), based on current U.S. Department of Agriculture dietary guidelines, found no association between the highest HEI score and ovarian cancer risk for any specific food group.[36] A systematic review of the role of diet in ovarian cancer included only prospective studies, with at least 200 reported cases in the publications.[37] Twenty-four publications from ten cohort studies were reviewed and no dietary factors were consistently associated with the risk of ovarian cancer.

Aspirin and nonsteroidal anti-inflammatory drugs

A systematic review and meta-analysis of 21 observational studies found a decreased risk of invasive ovarian cancer associated with aspirin use (RR, 0.88; 95% CI, 0.79–0.98), but no statistically significant association with nonsteroidal anti-inflammatory drugs (NSAIDs).[38] A study published subsequent to that review examined NSAID use and ovarian cancer risk in the National Institutes of Health-AARP Diet and Health Study. No association was observed between the development of ovarian cancer and regular aspirin use (RR, 1.06; 95% CI, 0.87–1.29) or NSAID use (RR, 0.93; 95% CI, 0.74–1.15).[39] A population-based case-control study [40] of 902 incident cases and 1,802 population controls observed a decreased risk of ovarian cancer associated with continual use (0.71; 95% CI, 0.53–0.97) or low-dose daily use (0.72; 95% CI, 0.53–0.97). In that study, selective cyclo-oxygenase-2 NSAIDs but not nonselective NSAIDs were associated with a decreased risk of ovarian cancer (OR, 0.60; 95% CI, 0.39–0.94). A cohort analysis of about 200,000 women in the Nurses' Health Studies, which used detailed data about the intensity and duration of aspirin use over time, showed a reduced HR for ovarian cancer of 0.77 (95% CI, 0.61–0.96) for low-dose aspirin use (≤ 100 mg/d) but no reduction for standard-dose aspirin use (HR, 1.17; 95% CI, 0.92–1.49).[41]

Perineal talc exposure

The weight of evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer. Results from case-control and cohort studies are inconsistent. A meta-analysis of 16 studies observed an increased risk with the use of talc (RR, 1.33; 95% CI, 1.16–1.45); however, a dose response relationship was not found.[42] A pooled analysis from the Ovarian Cancer Association Consortium, composed of multiple case-control studies, included 8,525 cases and 9,859 controls, found a modest increased risk of epithelial ovarian cancer associated with genital powder use (OR, 1.24; 95% CI, 1.15–1.33), but the trend across increasing lifetime number of applications was not statistically significant (P trend = .17).[43] A population-based case-control study of African American women in the United States found an association between genital powder use and risk of epithelial ovarian cancer (OR, 1.44; 95%

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CI, 1.11–1.86).[44] In this study of 584 cases and 745 controls, a dose-response relationship for *any* genital powder use was reported. Specifically, among *any* genital powder use, daily powder use was associated with increased adjusted OR of developing ovarian cancer (OR, 1.71; 95% CI, 1.26–2.33) compared with less than daily use (OR, 1.12; 95% CI, 0.80–1.58). A cohort study among nurses did not observe a risk of ovarian cancer associated with perineal talc use (RR, 1.09; 95% CI, 0.86–1.37) and there was no evidence of increased risk with increasing frequency of use.[45] Another prospective study, The Women’s Health Initiative, examined the association between perineal powder use and the development of ovarian cancer among 61,576 women without a history of cancer at enrollment and who provided exposure information. Among this group, 429 cases of ovarian cancer occurred. Powder use on genitals, sanitary napkins, and diaphragms was examined individually and as a combined exposure. Women were followed for a mean of 12.4 years. An association of ovarian cancer with ever-use was not found when analyzed either by individual method of exposure or by overall combined exposure. The observed risk (hazard ratio) for combined exposure to perineal powder was 1.06 (95% CI, 0.87–1.28) and there was no increased risk observed for increasing duration of use.[46]

Areas of Uncertainty

Ovarian hyperstimulation due to infertility treatment

Controversy persists concerning the association between ovarian hyperstimulation and ovarian cancer. Results of a systematic review and meta-analysis of nine cohort studies comprised 109,969 women who were exposed to ovarian hyperstimulation for infertility treatment (i.e., *in vitro* fertilization [IVF]), with 76 incident ovarian cancer cases observed, provided inconclusive evidence for an association.[47] An increased risk of ovarian cancer was observed when the comparison group was the general population (RR, 1.50; 95% CI, 1.17–1.92), but no statistically significant increased risk was observed when the reference group was unexposed infertile women (RR, 1.26; 95% CI, 0.62–2.55). A major limitation was that only one of the cohort studies included in the meta-analysis had a follow-up period longer than 10 years for those exposed to IVF.

A Cochrane systematic review that included 11 case-control studies and 14 cohort studies, for a total of 186,972 women, was also indeterminate for an association. Summary statistics were not calculated because of methodological and clinical heterogeneity. Among seven cohort studies that compared treated women with untreated subfertile women, no excess risk was noted in association with hyperstimulation medications. Two cohorts noted an increased risk of twofold to fivefold when treated women were compared with the general population. An increased risk of borderline ovarian tumors was noted in three case-control studies and two cohort studies. Overall, the authors concluded there was no convincing evidence that an increased risk of invasive ovarian tumors was associated with fertility drug treatments.[48]

After the Cochrane review, a follow-up study of an infertility cohort [49] was published. A retrospective cohort of 9,825 women enrolled between 1965 and 1988 was followed through 2010. Ovarian cancer occurred in 85 women. Overall, there was no association between ovarian cancer and clomiphene citrate (RR, 1.34; 95% CI, 0.86–2.07) or gonadotropins (RR, 1.00; 95% CI, 0.48–2.08). Among the subgroup of women who remained nulligravid after treatment, an increased risk of ovarian cancer was associated with clomiphene citrate (RR, 3.63; 95% CI, 1.36–9.72); no increased risk was observed among women who successfully conceived after being treated, compared with women who were not treated.

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Changes to This Summary (03/01/2019)

The PDQ cancer information summaries are reviewed regularly and updated as new information becomes available. This section describes the latest changes made to this summary as of the date above.

Description of the Evidence

Updated [statistics](#) with estimated new cases and deaths for 2019 (cited American Cancer Society as reference 1).

Added [text](#) about a cohort analysis of about 200,000 women in the Nurses' Health Studies, which used detailed data about the intensity and duration of aspirin use over time, that showed a reduced hazard ratio for ovarian cancer of 0.77 for low-dose aspirin use but no reduction for standard-dose aspirin use (cited Barnard et al. as reference 41).

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About This PDQ Summary

Purpose of This Summary

This PDQ cancer information summary for health professionals provides comprehensive, peer-reviewed, evidence-based information about ovarian, fallopian tube, and primary peritoneal cancer prevention. It is intended as a resource to inform and assist clinicians who care for cancer patients. It does not provide formal guidelines or recommendations for making health care decisions.

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Updated: March 1, 2019

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Exhibit 84

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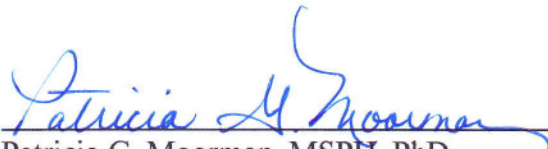
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**RULE 26 EXPERT REPORT OF
PATRICIA G. MOORMAN, MSPH, PHD**

Date: November 16, 2018


Patricia G. Moorman, MSPH, PhD

Scientific Review of the Epidemiologic Evidence on Talc Use and Ovarian Cancer

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Background and Qualifications of Patricia G. Moorman, MSPH, PhD

I am a tenured professor in the Department of Community and Family Medicine, Duke University School of Medicine, Durham, NC and a member of the Cancer Control and Population Sciences Program in the Duke Cancer Institute. I am an epidemiologist with more than 25 years of experience in conducting research on women's health issues including ovarian cancer, breast cancer and menopause. Attached as Exhibit A to this report is a current copy of my curriculum vitae.

Education

I received a Bachelor of Science degree with distinction in pharmacy from the University of Kansas in 1980. I pursued graduate studies in epidemiology in the School of Public Health at the University of North Carolina-Chapel Hill, earning a Master of Science in Public Health (MSPH) in 1989 and a Doctor of Philosophy (PhD) degree in 1993.

Professional Experience

I have held positions in academic institutions since I completed my PhD, beginning as a research assistant professor in the Department of Epidemiology at the University of North Carolina-Chapel Hill from 1994 through 1996. From 1997 to 2000, I was an associate research scientist in the Chronic Disease Epidemiology division of the Yale University School of Public Health. I came to Duke University School of Medicine as an assistant professor in 2000, progressing through the academic ranks from associate professor, associate professor with tenure to my current position as professor in Community and Family Medicine. I also serve as the director of the Clinical Research Unit for the Department of Community Medicine and am a member of the Senior Faculty Advisory Committee for the Office for Research Mentoring in the School of Medicine. In addition, I am an adjunct faculty member in the Department of Epidemiology at the University of North Carolina-Chapel Hill.

Compensation and Testimony

My hourly billing is \$400. I have given deposition testimony in one case (Gail Ingham, et al., v. Johnson & Johnson, et al., Case No. 1522-CC10417-01, Circuit Court of the City of St. Louis, Division 10) and have not testified at trial in the last four years.

Research Interests and Experience

My primary research interests are in the area of women's health issues, with a particular focus on studying racial differences in risk factors and outcomes. I have had funding from the National Institutes of Health (NIH) for more than 20 years, which has supported my research in ovarian cancer, breast cancer and ovarian function after hysterectomy. Three of the key studies in my research career are: 1) the African American Cancer Epidemiology Study (AACES), a multi-center, case-control study of ovarian cancer in African American women,¹ 2) the Carolina Breast Cancer Study, which is one of the largest studies focused on understanding racial differences in breast cancer risk and outcomes,² and 3) the Prospective Research on Ovarian Function (PROOF) Study, a cohort study designed to examine risk for ovarian failure after premenopausal hysterectomy.³

Each of these studies involved primary data collection, meaning that the investigative team designed the data collection procedures, developed the surveys, recruited study participants and obtained questionnaire data and biological specimens from the participating women. Each study has made unique contributions to the scientific literature.

AACES has enrolled more than four times as many African-American women with ovarian cancer than any other study and is providing the most comprehensive epidemiologic data on ovarian cancer risk factors in this population to date.⁴⁻⁶ The Carolina Breast Cancer Study likewise provided key data on risk factors in African American women and was the first study to describe the markedly higher prevalence of the poor-prognosis basal subtype of breast cancer in young African American women.⁷⁻¹¹ The PROOF study is the largest prospective study of ovarian function after pre-menopausal hysterectomy and demonstrated that women

undergoing hysterectomy with ovarian conservation were at significantly increased risk for earlier menopause as compared to women who did not have a hysterectomy.^{3,12}

Our study team published an analysis of talc exposure and ovarian cancer in 2016, using data from AACES.¹³ This peer-reviewed paper, published in *Cancer Epidemiology, Biomarkers and Prevention*, was the first epidemiologic study of talc use and ovarian cancer that was focused exclusively on African American women. Our analyses found both a high prevalence of talc use in this study population and a statistically significantly increased risk for ovarian cancer among talc users. This paper was published prior to my involvement in litigation related to talc and ovarian cancer.

I have also been a co-investigator on the North Carolina Ovarian Cancer Study, which was a precursor to the AACES study. Data from this study were included in Terry, et al.'s¹⁴ 2013 analysis of genital powder use and ovarian cancer that pooled from data from eight case-control studies. I am currently an investigator in the Ovarian Cancer in Women of African Ancestry (OCWAA) consortium. The OCWAA consortium, which was initiated in 2016, is a multi-center collaboration that aims to bring together data from case-control and cohort studies to evaluate similarities and differences between African American and white women in ovarian cancer risk factors and outcomes.

In addition to these studies, I am an investigator with the Evidence Synthesis Group in the Duke Clinical Research Institute, a team of researchers that conducts evidence reviews of the scientific literature. I have worked with this group on a number of systematic reviews and meta-analyses on women's health issues including an evaluation of the benefits and risks of oral contraceptive use for primary prevention of ovarian cancer¹⁵⁻¹⁷ funded by the Agency for Healthcare Research Quality, and an evaluation of the benefits and harms of breast cancer screening¹⁸ funded by the American Cancer Society to help inform their screening mammography recommendations.¹⁹

I am an author on more than 130 scientific publications, with more than 50 of them directly related to ovarian cancer. The ovarian cancer papers address a wide variety of risk factors including reproductive and hormonal factors, lifestyle characteristics, genetic factors, and talcum powder products. The main focus of the manuscripts on which I have been the lead

author has been ovarian cancer risk factors in African American women and the effects of reproductive characteristics, hormones and other medications on risk for ovarian cancer.^{5,17,20-}

²³ The papers have been published in some of the leading journals in the field of epidemiology, gynecology and cancer including the *American Journal of Epidemiology*, *Cancer Epidemiology Biomarkers and Prevention*, *Obstetrics & Gynecology* and *Journal of Clinical Oncology*.

My teaching experience includes courses in Cancer Epidemiology for graduate students in public health and Evidence-Based Medicine for physician assistant students. A primary emphasis of these courses has been for the students to gain an understanding of the advantages and disadvantages of different types of studies used in clinical and epidemiologic research. In particular, the Evidence-Based Medicine course is designed to help the students learn how to critically appraise the medical literature and apply findings to clinical practice. In addition, I have mentored at the individual level public health graduate students and medical students.

I serve as an editorial reviewer for numerous journals and have served as a peer reviewer of grant applications on several dozen study sections over that past twenty years. I have reviewed NIH grants for a variety of funding mechanisms ranging from small grants (R03) to large multi-project applications (SPORC grants and Program Projects). I also have served as both peer reviewer and study section chair for the Susan G. Komen for the Cure Foundation and the Department of Defense Ovarian Cancer and Breast Cancer Research Programs.

In summary, in a career spanning more than 25 years, I have devoted my efforts to understanding factors that affect risk for ovarian cancer, breast cancer and menopause. I have conducted original research, giving me a deep appreciation of the advantages and disadvantages of different study designs and the challenges of collecting high-quality data for making etiologic inferences. I also have conducted research involving synthesis of the published literature, with the goal of informing decisions based on the best available evidence. A large proportion of my publications have focused on the epidemiology of ovarian cancer, and many of the others focused on breast cancer or menopause have relevance to ovarian cancer because of shared risk factors for the conditions. Based on my education, experience, and expertise, I

am highly qualified to assess the literature on the use of talc in relation to ovarian cancer and provide an expert opinion to a reasonable degree of medical certainty.

Purpose

The purpose of this report is to summarize the epidemiologic evidence related to talc use and ovarian cancer risk and to make a judgment as to whether there is sufficient evidence, based on the totality of evidence from epidemiologic investigations as well as laboratory and mechanistic studies, to conclude with a reasonable degree of scientific certainty that talcum powder use is a causal factor for ovarian cancer.

Throughout the report, the term "talc" will be used to refer to talcum powder products, recognizing that commercial talc products can contain asbestos, talc containing asbestiform fibers (e.g., talc occurring in a fibrous habit), heavy metals such as nickel, chromium and cobalt and fragrances.

Role and Importance of Epidemiologic Studies

It is important to bear in mind that epidemiologic research on factors that are thought to increase risk for cancer in human populations will consist of observational rather than experimental studies. As with most other now-known carcinogens, including cigarette smoke, it is both ethically wrong and pragmatically impossible to conduct randomized controlled trials to investigate whether a given exposure increases risk for cancer in humans. The judgment as to whether talc causes ovarian cancer will be based on epidemiologic studies in which the investigators collected and analyzed information on exposures (i.e., talc use and other risk factors) that the study participants chose to use, rather than studies in which exposures were randomly assigned to the study subjects in an experimental setting.

Observational study designs used in the study of talc and ovarian cancer include cohort and case-control studies, both of which are well-established and generally accepted methods for studying cancer etiology. In a prospective cohort study, a large group of individuals (the cohort) is identified and exposure to various factors hypothesized to affect risk of disease is

assessed at the time of enrollment (baseline). The cohort is followed over time and the analyses focus on whether the exposed group is more or less likely to develop the outcome of interest than the unexposed group. Some of the prominent advantages of cohort studies are that multiple outcomes/diseases can be assessed within the cohort and exposure assessment precedes the development of the disease, limiting recall bias. However, a primary disadvantage of cohort studies, particularly in relation to cancer etiology studies, is that they must enroll tens of thousands of subjects and follow them for long periods of time to accrue enough cases to have a well-powered study. In addition, if cohort studies do not update exposure information after the baseline assessment, the exposure of some individuals in the cohort may be misclassified.

Case-control studies identify individuals with the disease of interest and an appropriate control group of individuals without the disease and assess exposures that are thought to increase or decrease the risk of the disease. The investigators then analyze whether cases are more likely than the controls to have a given exposure. Case-control studies focus on a single disease, therefore they typically collect more detailed risk factor information for that disease than cohort studies. A major advantage of case-control studies is that they are a more efficient design for studying diseases that are less common or have a long latency period. Therefore, they are very commonly used for etiologic studies of cancer. A disadvantage of case-control studies is that they collect exposure information for the cases after they have already been diagnosed with the disease, which raises concerns that cases may recall exposures differently from controls.

Cohort studies and case-control studies each have advantages and disadvantages for assessing talc as a risk factor for ovarian cancer, and one study design is not clearly superior to the other. In addition, specific details related to the conduct of the study such as methods of exposure assessment, length of follow-up and choice of control group can impact the validity of the findings and the interpretation of results. Therefore, rather than making a judgment based only on the overall study design, the evaluation and interpretation of the findings of the studies must consider the strengths and weaknesses of the individual studies. As the results of the

studies are described and evaluated in this report, specific advantages and disadvantages of individual studies will be discussed in more detail.

In contrast to studies on laboratory animals, studies on humans are subject to more variation in exposure assessment and it is impossible to control all other factors that may contribute to disease risk. For these reasons, judgments on causality from epidemiologic research typically are not based on a single study or even a few studies, but are based on the totality of evidence from multiple studies conducted in different study populations, in different locations and across different time periods. Evidence from the epidemiologic investigations is combined with relevant studies from other disciplines, including pathology, animal and mechanistic studies, to make an assessment of the evidence for a causal association between genital exposure to talcum powder and ovarian cancer.

Methodology

The methodology I used to assess the epidemiologic evidence on talc use as a causal risk factor for ovarian cancer involved conducting a literature search on PubMed using the terms “ovarian cancer” and “talc” to identify all relevant original studies, systematic reviews, meta-analyses, editorials and commentaries (search most recently updated on October 29, 2018). The search I did returned 131 articles, all of which were systematically considered and assessed as to their relevance to talc as a risk factor for ovarian cancer. Twenty-nine articles were not directly relevant to the question at hand (mostly addressing talc in the treatment of malignant pleural effusions). Of the remaining 101 articles, 36 were reports of original epidemiologic studies directly addressing genital talc exposure and ovarian cancer or meta-analyses of such studies.^{14,24-56} Other articles retrieved included studies of occupational talc exposure,⁵⁷⁻⁶² other original research articles that were not specifically epidemiologic studies of genital talc and ovarian cancer (e.g., studies of endometrial cancer, pathology studies, animal studies, etc.)⁶³⁻⁸⁰ and reviews, commentaries and letters^{60,81-120} I also examined reference lists from key articles to identify any additional relevant studies. In addition, I reviewed relevant studies as well as documents provided during the course of discovery process.

The primary focus of my review is the epidemiologic studies of genital talc exposure and ovarian cancer and the meta-analyses, with supporting information from other types of publications, including animal, pathology and mechanistic studies used as appropriate to address biological mechanisms underlying the association between talc use and ovarian cancer.

As I evaluated the individual epidemiologic studies (case-control and cohort studies) that described the risk for ovarian cancer associated with talc use, I did not weight one design more heavily than the other because there are advantages and disadvantages to each design for evaluating talc as a cause of ovarian cancer. I considered the potential biases of individual studies, both those that supported and those that did not support an association between talc and ovarian cancer, and how those biases may have impacted the findings. As I describe in this report, some biases have the potential to lead to an overestimate of the relative risk (e.g. recall bias in case-control studies) while others could result in an underestimate of the relative risk (e.g. incomplete ascertainment of talc use in the cohort studies).

I also considered the studies that combined data from multiple studies – meta-analyses or pooled analyses from multiple case-control studies. These types of analyses are often considered to be some of the strongest evidence for a causal association between an exposure and disease as they provide an estimate of the relative risk that is more statistically robust than individual studies. Data from meta-analyses are particularly important for evaluating exposure-disease relationships such as talc and ovarian cancer where the relative risks from most individual studies are approximately 1.2 to 1.5.

As is standard in epidemiologic research, my assessment of whether there is a causal association between talc use and ovarian cancer was guided by the aspects of a causal relationship described by Bradford Hill during the 1960's. Sir Austin Bradford Hill's writings on causal inference provide an accepted framework for assessing whether a given exposure is a cause of a specific outcome.¹²¹ The aspects of the associations that Hill described are: Strength, Consistency, Specificity, Temporality, Biological Gradient, Plausibility, Coherence, Experiment and Analogy. As his writings clearly state, these viewpoints or perspectives should be taken into account when assessing causality, but are not to be considered absolute criteria and not all must be checked off to make a conclusion of a causal relationship. Specifically, he states "What

I do not believe is that we can usefully lay down some hard-and-fast rules of evidence that must be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*.” This list of viewpoints was used to guide my assessment of the scientific literature on talc use and ovarian cancer.

It is important to point out that, in the end of this process, the assessment of whether a substance is or is not a causal risk factor for a given disease or condition involves scientific judgment that is made by considering and weighing the evidence. In any given case, it is not unusual for scientists and epidemiologists to weigh the Hill factors differently in reaching a conclusion on the causal inference in question. For example, scientists for many years debated the evidence that cigarette smoking causes lung cancer or asbestos causes lung disease.

Epidemiologic Studies Reviewed

Since 1982, when the first case-control study describing an increased risk for ovarian cancer associated with talc use was reported by Cramer, et al.,⁵⁰ more than two dozen additional reports of epidemiologic studies have been published.^{13,14,24-36,38-44,46-49,51-55,122,123} In some instances, data from a particular study were included in more than one publication, due either to an additional analysis of data from a cohort study with longer duration of follow-up (e.g.,^{31,34}) or to analyses that combined data from more than one study (e.g.,^{14,25}). Included in these publications are seven meta-analyses published between 1992 and 2018 that combined overall results from nine to 27 studies^{35,51,52,54-56} and a pooled analysis published in 2013 that combined individual level data from eight case-control studies.¹⁴

Strength and Consistency of the Association

The first two aspects of the causal relationship described by Bradford Hill, strength and consistency of association, are deeply intertwined. While Bradford Hill referenced the assumption that a larger relative risk is more likely to reflect a causal association, Hill also clearly stated that we should not be “too quick to dismiss a cause-and-effect hypothesis merely

on the grounds that the observed association appears to be slight. There are many occasions in medicine when this is in truth so.”¹²¹

Seven meta-analyses of genital talc exposure and ovarian cancer^{35,44,51,52,54-56} calculated summary relative risks that were very consistent across the publications, ranging from 1.22 to 1.36, all with 95% confidence intervals excluding 1, indicating that women who reported talc use were at statistically significant increased risk for ovarian cancer. Similarly, the pooled analysis of eight case-control studies reported an overall odds ratio of 1.24 (95% confidence interval (CI) 1.15 – 1.33).¹⁴

To put this in context, it is useful to compare the epidemiologic data related to the strength of the association between genital talc use and ovarian cancer with some other well-accepted exposure-disease associations that have relative risks of similar magnitude and are generally accepted to be causal associations. Some examples of such associations and the relative risks from these exposures estimated from meta-analyses are:

1. Oral contraceptive use and breast cancer, relative risk 1.08 (95% CI 1.003-1.165) for ever versus never use and relative risk 1.21 (95% CI 1.04-1.41) for current or recent use versus never use¹⁶
2. Menopausal estrogen use and breast cancer, relative risk 1.20 (95% CI 1.06-1.37) for more than 5 years use versus no use¹²⁴
3. Passive smoking (also referred to as environmental tobacco exposure or secondhand smoke) and lung cancer, relative risk 1.27 (95% CI 1.17-1.37) for ever versus never exposure to a spouse who smoked¹²⁵
4. Residential radon exposure and lung cancer, relative risk 1.29 (95% CI 1.10-1.51) for highest versus lowest exposure¹²⁶
5. Trichloroethylene exposure and kidney cancer, relative risk 1.32 (95% CI 1.17-1.50) for occupational exposure.¹²⁷

Each of these exposure/disease associations is widely accepted as a causal relationship in the scientific community and has been judged to be a causal association by the International Agency for Research on Cancer (IARC).^{128-130 131} The estimates of the relative risks for these associations from meta-analyses or pooled analyses are approximately 1.25,^{16,124-126,132,133}

which is in the range of estimates of the relative risk from meta-analyses and pooled analyses for the association between genital talc use and ovarian cancer. Therefore, we have evidence of well-established causal associations in which the magnitude of the relative risk is very similar to what has been reported for genital talc use and ovarian cancer.

It is instructive to compare in more detail the epidemiologic data on passive smoke exposure to that of talc and ovarian cancer. Passive smoke exposure, like talc, is a very common exposure in the population that can only be assessed retrospectively through self-report, therefore it is difficult to determine the precise level of exposure. In a meta-analysis of 55 studies published between 1981 and 2006 that examined the risk for lung cancer in never smoking women with passive smoke exposure from their spouses, Taylor, et al.¹²⁵ reported a pooled relative risk of 1.27 (95% CI 1.17-1.37). The relative risks from individual studies ranged from 0.66 to 2.57, with 44 of the 55 (80%) individual studies reporting a relative risk or odds ratio >1. In the individual studies, only 10 of 55 (18%) reported statistically significant associations (2 of 7 cohort studies, 3 of 25 case-control studies with population-based controls and 5 of 23 case-control studies). These data show that among the many epidemiologic studies that assessed passive smoke exposure as a risk factor for lung cancer, not all had statistically significant findings and some even reported relative risks less than one, yet the overall conclusion from the totality of the evidence is that passive smoke exposure is causally associated with lung cancer.

The most recent meta-analysis published in 2018 on talc and ovarian cancer by Pennikilampi et al. reported a pooled relative risk of 1.31 (95% CI 1.24-1.39) with values from individual studies ranging from 0.73 to 3.90.⁵⁶ This result is consistent with other meta-analyses performed. Twenty-four of the 26 (92%) studies reported a relative risk or odds ratio >1, and statistically significant associations were reported in 14 of the 26 (54%) studies. This comparison illustrates that as compared to the well-established causal association between passive smoke exposure and lung cancer, the association between talc and ovarian cancer has a pooled relative risk estimate of similar magnitude with a greater proportion of the studies reporting relative risks >1 and a greater proportion reporting statistically significant

associations suggesting the evidence for talc and ovarian cancer is as significant as for passive smoke exposure and lung cancer.

These comparisons also illustrate the importance of meta-analyses in epidemiologic research when considering exposures for which the strength of association is approximately 1.5 or less. Individual studies, especially those with smaller samples sizes, may not detect a statistically significant increased risk. When the increased risks in this range are seen repeatedly, even when individual studies are not statistically significant, meta-analysis allows the data to be aggregated to make a conclusion that is more robust statistically. When combining these studies through meta-analysis, the totality of the data shows that there is indeed a statistically significant link between genital talc use and ovarian cancer. This observation has been quite consistent, with findings replicated in studies conducted by different teams of investigators, in different geographic locations within and outside the United States, in different race/ethnic groups and over a span of several decades.

In conjunction with the strength of the association, it is also critical to consider the prevalence of the exposure in the population when evaluating its public health impact. A risk factor that is less strongly associated with a disease but has a high prevalence in the population can be responsible for more cases of the disease than a risk factor that is more strongly associated with the disease but has a low prevalence in the population. A measure of the contribution of a risk factor to a disease is the population attributable fraction (PAF), which is defined as the proportion by which the incidence rates of the outcome in the population would be reduced if the exposure was eliminated.¹³⁴ Wu et al.²⁶ calculated the PAF for ovarian cancer related to talc exposure in their multi-ethnic case-control study in Los Angeles. The odds ratio for genital talc use was 1.46 (95% CI 1.27 – 1.69) and the prevalence of use was 41% among the cases and 31% among the controls. The PAFs for the different ethnic groups ranged from 12.2 to 15.1%, which is interpreted as the proportion of ovarian cancer cases that theoretically could be prevented if genital talc use in the population could be eliminated and there were no changes in other risk factors. In other words, of the estimated 22,440 cases of ovarian cancer diagnosed in 2017,¹³⁵ approximately 3,300 of them could theoretically have been prevented if women had not used genital talc. The PAF calculation demonstrates that even with an

estimated relative risk for genital talc use of less than 1.5, its high prevalence of use means that it contributes to a substantial proportion of the ovarian cancer cases in the population.

The overall associations seen in the talc-ovarian cancer meta-analyses as well as in many of the individual studies are statistically significant, indicating an increase in risk of approximately 25 to 30%. While not as high as other relationships like smoking and lung cancer, these relative risks are in line with other generally accepted causal relationships (e.g., second hand smoke and lung cancer). I consider the strength of the association seen in the talc-ovarian cancer epidemiologic studies, to be an important factor in favor of a causal relationship between talc and ovarian cancer, particularly when considered along with the consistency of the association seen across these studies.

As described above, among the more than two dozen studies that have reported on the association between talc use and ovarian cancer, the vast majority of them reported relative risks or odds ratios greater than one, indicating strong consistency in the direction of the effect. The findings from the multiple studies are summarized in seven meta-analyses published since 1992, including two published in 2017-18, that combined overall results from six to 27 studies assessing genital talc exposure and ovarian cancer^{35,51,52,54,55 56 44} and in a pooled analysis published in 2013 that combined individual level data from eight case-control studies.¹⁴ Of the 27 studies included in Berge et al.'s 2017 meta-analysis⁵¹, 24 were case-control studies (18 population-based,^{13,23,25,29,30,32,33,38,39,41,42,44,45,47,50,123,136,137} 5 hospital based,^{36,43,46,49,122} and 1 with both hospital and population controls⁴⁸) and three were prospective cohort studies^{24,27,31}. The calculated overall relative risks for all studies combined in these meta-analyses were 1.3 (95% CI 1.1 – 1.6),⁴⁴ 1.27 (95% CI 1.09-1.48),⁵⁵ 1.36 (95% CI 1.24-1.49),³⁵ 1.33 (95% CI 1.16-1.45),⁵⁴ 1.35 (95% CI 1.26 - 1.46),⁵² 1.22 (95% CI 1.13-1.30)⁵¹ and 1.31 (95% CI 1.24-1.39)⁵⁶ and 1.24 (95% CI 1.15-1.33) in the pooled analysis of eight case-control studies.¹⁴ The conclusions from these analyses were quite consistent, even with additional data accumulating over time, indicating that women who used talc products as compared to women who reported no talc use were at 22 to 36% increased risk for ovarian cancer.

When considering the consistency from a number of different studies and meta-analysis, an epidemiologist should evaluate potential sources of bias including but not limited

to publication bias, recall bias, selection bias and information bias. I discuss each of these below.

Publication Bias: When considering a body of epidemiologic evidence from multiple studies, several concerns arise about the completeness of the published data and whether there is selective publishing of studies that find significant positive associations. These concerns were addressed by two distinct analyses conducted in the most recent meta-analyses by Berge, et al. (2017) and Penninkilampi and Eslick (2018).^{51,56} The first approach reported was a funnel plot, which is a graphical technique that plots the relative risks derived from the studies on one axis and the standard error of the relative risk (an indicator of the size of the study) on the other. The concept driving this approach is that studies should cluster around the “true” relative risk in the population. Due to random statistical variation, some studies will have relative risks that are higher than the true relative risk and some will be lower than the true relative risk. As sample sizes increase, there should be more precise estimates of the relative risk, therefore larger studies would be expected to produce estimates closer to the true relative risk whereas smaller studies may produce results that deviate further from the relative risk in the overall population. When the study results are plotted, one would expect them to fall into a funnel shape, with the larger studies at the point of the funnel, clustered around the true relative risk in the population, and smaller studies, with more variation in results, showing greater deviation from the average, forming the wide part of the funnel. Notably, in these meta-analyses, the two studies with the highest relative risk estimates (Chen, et al.⁴⁵ with a relative risk of 3.90 and Godard, et al.³⁸ with a relative risk of 2.49) and the two studies with the lowest relative risks (Hartge, et al.⁴⁹ and Gonzalez, et al.²⁴) all had a modest number of cases (≤ 170).

A funnel plot provides a method for assessing publication bias, i.e., the bias that results from studies with statistically significant findings being more likely to be published than studies that show no association. If one is concerned that studies that showed no association between the exposure and outcome are less likely to be published, the funnel plot allows the visual assessment of this potential bias. A lack of symmetry in the funnel plot, with a deficit of studies showing no association between the exposure and outcome, would be an indication of

publication bias. The papers by Berge, et al.⁵¹ and Penninkilampi and Eslick⁵⁶ which are the only meta-analyses that specifically addressed publication bias, concluded that there was no serious publication bias based on both visual inspection of the funnel plot and a statistical assessment of the data from the funnel plot. Therefore, there is a high level of confidence that there has not been preferential publication of studies that found a positive association between talc and ovarian cancer.

A second approach used by Berge, et al.⁵¹ was a cumulative meta-analysis, in which they showed the estimated summary relative risks over time from the first published report in 1982 through the most recently published studies in 2016. The plot showed that after the first initial reports, the overall summary estimates stabilized with estimates in the range of 1.2 to 1.25 over the last 25 years even as more and more data accrued from additional published studies.

These quantitative analyses indicate that it is unlikely that there is publication bias in the talc and ovarian cancer literature (i.e., the analyses do not suggest that studies that found talc use to be a risk factor for ovarian cancer were more likely to be published than those that found no association). Furthermore, from a qualitative perspective, it is also unlikely that there is a substantial risk for publication bias. Given the considerable public health interest in the risk for ovarian cancer associated with a widely-used cosmetic product, it is probable that any well-designed and conducted study that addressed this question would be published, even if it had null findings. Notably, one of the most recent studies, the Sister Study,²⁴ was published even though it found no increased risk for ovarian cancer associated with talc use.

While the overall conclusions from the meta-analysis and pooled analyses are quite consistent, with an overall statistically significant estimate of the relative risk in the range of approximately 1.2 to 1.3, it is important to consider possible reasons for heterogeneity of the estimates between individual studies.

Among the individual studies that have examined the association between talc use and ovarian cancer, the majority have been case-control studies, with only three prospective cohort studies addressing this research question. The meta-analysis by Berge, et al.⁵¹ noted that the summary relative risk was driven by the stronger associations observed for case-control studies

(relative risk = 1.26 (95%CI 1.17 – 1.35) than for cohort studies (relative risk = 1.02 (95% CI 0.85 – 1.20), which leads one to try to understand possible reasons for the differences by study design and to consider the relative advantages and disadvantages of the different study designs, specifically in relation to the study of talc and ovarian cancer. While the cohort studies do not show a statistically significant association for ever use of talc and ovarian cancer overall, the recent meta-analysis by Penninkilampi and Eslick⁵⁶ reported a statistically significant association with the invasive serous subtype of ovarian cancer, which is both the most common subtype and the one with the worst prognosis.

Case-Control Studies – Strengths and Weaknesses: Case-control studies, which are very commonly used in cancer epidemiology, have particular advantages for studying a relatively uncommon cancer like ovarian cancer, which has an annual incidence (number of new cases) in the United States of approximately 11 cases per 100,000 women.¹³⁸ In this study design, women with ovarian cancer (the case group) are identified by the research team, typically through a cancer registry, shortly after receiving their diagnosis. A control group of women who do not have the disease are also identified and recruited for the study. Both the cases and the controls provide information on their past exposure history. In a typical case-control study, the study participants complete an extensive questionnaire focusing on a broad range of exposures that are hypothesized to either increase or decrease the risk for cancer. In regard to ovarian cancer, a typical questionnaire will include questions on demographic characteristics, reproductive characteristics like pregnancy and contraception, medical characteristics, family history of cancer and lifestyle characteristics such as dietary factors, smoking history, physical activity and talc use. Notably, some of the factors queried about are expected to increase risk (e.g., family history of ovarian or breast cancer, estrogen use during menopause, talc), whereas others are associated with reduced risk (e.g., oral contraceptive use, pregnancies).

One major advantage of a case-control study is that it is possible to identify and recruit a large number of cases within a relatively short timeframe. To illustrate this point, I will use the example of AACES, the case-control study that my colleagues and I initiated in 2010 to study ovarian cancer in African American women and which was the source of the data we used for our 2016 paper on talc and ovarian cancer.^{1,13} We have enrolled more than 600 women with

ovarian cancer and more than 700 control women over a period of approximately 6 years, making it by far the largest study of ovarian cancer in African American women. When the grant application was originally submitted to the National Cancer Institute, one reviewer expressed the opinion that a cohort study would be preferable to the case-control design we proposed. In our response to the review, we pointed out that a prospective cohort study was not feasible for studying ovarian cancer in this population if we hoped to obtain meaningful information in a reasonable timeframe. The Black Women's Health Study, a large prospective cohort study, enrolled approximately 60,000 women starting in 1995 with the goal of studying a wide variety of health outcomes in this population. (<https://www.bu.edu/bwhs/>) In regard to ovarian cancer, after 18 years of follow-up, only 115 cases of ovarian cancer had been diagnosed among women in the cohort.¹³⁹ Although a cohort of 60,000 women is a very large epidemiologic cohort, it is still inadequate to study a relatively uncommon disease like ovarian cancer in a time-efficient manner. We successfully made the argument to the reviewers that a case-control study was the only feasible way to investigate the etiology of ovarian cancer in a timely manner in the African American population. This example illustrates why it is to be expected that the majority of the epidemiologic studies of ovarian cancer would be case-control studies.

Although case-control studies are commonly used in epidemiologic studies of cancer, there are potential biases associated with this study design, including selection bias and recall bias. In this study design, the investigator must select a control group of individuals without the disease being studied as a comparison group to determine the relative frequency of the exposures in the case group as compared to the control group. The goal of selecting a control group is to identify a group that is representative of the population from which the cases arose. This is often stated in textbooks as if someone in the control group were to develop the disease being studied, s/he would have been selected as a case for the study. There are many possible strategies for identifying and recruiting population-based controls, including the use of town registry books,^{25,50} telephone recruitment through random digit dialing^{13,25,29}, neighborhood recruitment,³⁰ driver's license records²⁵ and electoral rolls.¹²³ In hospital-based case-control studies, controls are typically selected from other hospitalized patients, with different studies

applying different criteria for eligible diagnoses among the controls, including other cancer diagnoses or specific non-cancer diagnoses.^{36,43,46,49,122}

Among the studies included in the recent meta-analyses, six were hospital-based case-control studies.^{36,43,46,48,49,122} The individuals that comprised the control group varied between these studies including patients with non-gynecologic malignancies,³⁶ patients treated for conditions other than gynecologic or malignant diseases,¹²² patients treated for conditions other than those related to reproductive history or oral contraceptive use,⁴⁶ patients treated for conditions other than gynecologic, psychiatric, or malignant diseases or pregnancy,⁴⁹ both hospital patients and population-based controls⁴⁸ and hospital visitors.⁴³ While the use of hospital controls may be efficient, concerns are often raised as to whether the controls are representative of the population from which the cases arose in terms of the exposures they experienced or their underlying risk for cancer. This is a particular concern with the study by Wong, et al,³⁶ which is the largest of the hospital-based case-control studies and one that found no association between talc use and ovarian cancer (OR=0.92, 95% CI 0.24-3.62). The control group in this study was “female patients treated for non-gynecologic malignancies during the same period”. Standard epidemiologic textbooks (e.g., Rothman, *Modern Epidemiology*¹⁴⁰) state that controls should be selected from the same source population or study base that gives rise to the cases. It is difficult to make the argument that other cancer patients represent the source population from which the ovarian cancer cases arose, which suggests that this was a poor choice of a control group that could have led to biased findings.

Another of the hospital-based studies, the study by Tzonou et al.⁴³ which reported a relative risk of 1.05, also had a significant limitation. This study was conducted in Greece, and the overall prevalence of talc use in the study population was 3.5%. Given the small sample size and the low prevalence of exposure, this population was ill-suited to study the relation between talc use and ovarian cancer.

As noted in the meta-analysis by Penninkilampi and Eslick,⁵⁶ the hospital-based studies were older (published before 2000) and with the exception of the Wong study³⁶, all were smaller studies that included fewer than 200 cases. The summary odds ratios from the hospital-based studies was lower but not significantly different than the summary odds ratio from

population-based studies (OR 1.22 versus 1.33, respectively),⁵⁶ a result that is not surprising given the important limitations in some of the hospital-based studies.

While there is no ideal method for control selection, arguably population-based control recruitment is more likely to result in a control group that is representative of the population from which cases arose. All of the larger case-control studies that investigated talc use and ovarian cancer (i.e., those with more than 500 cases) were population-based,^{13,23,25,29,30,33,42,123,137} which should have minimized selection bias.

Recall Bias: Recall bias is another possible bias in case-control studies. Recall bias is defined as systematic error due to differences in accuracy or completeness of recall of prior events or experiences.¹³⁴ It is a concern with case-control studies because information on exposures is obtained through interviews or questionnaires completed after the cases have already been diagnosed with the disease. It is thought that people affected with a disease may have given more thought to possible causes of that disease and have more accurate recall of risk factors than a person serving as a control in the study.

A distinction is made between *recall bias*, which arises from cases recalling exposures differently than controls, and *inaccurate recall* of an exposure that is difficult to remember with precision. Recall bias, which is considered differential misclassification between cases and controls, can result in either an overestimate or underestimate of the true relative risk. Inaccurate recall that occurs to a similar degree in cases and controls is considered non-differential misclassification, and for a dichotomous outcome (e.g., ever vs. never use of talc) will typically result in an underestimate of the true relative risk. An exposure like talc use, especially when assessing use over many years, is clearly one that is subject to a certain amount of inaccurate recall. However, inaccurate recall alone would not result in the consistently increased relative risks observed in the vast majority of the case-control studies of talc use and ovarian cancer.

Therefore, recall bias, which theoretically could result in a biased estimate of the relative risk, must be considered. Situations where recall bias would be considered a particular threat to a study's validity would be: 1) the exposure of interest is one that could be considered sensitive (e.g., illicit drug use, induced abortions), 2) the study hypotheses are known to the

study subjects or interviewers, or 3) there has been considerable media attention focused on an exposure.

In regard to the first situation, genital talc use, while addressing a rather personal topic, would not be considered a particularly sensitive topic. One would not expect that women would be disinclined to report its use out of embarrassment or a desire to report what is perceived to be more socially acceptable as has been reported for exposures like induced abortion.¹⁴¹

As to the second point regarding the blinding of the interviewers and the study participants to the study hypotheses, this is standard practice in epidemiologic research. In addition, in the typical case-control study, the investigators are collecting a tremendous amount of questionnaire data to address numerous hypotheses and there is not a particular focus on a single exposure. As an example, the questionnaires from AACES and the North Carolina Ovarian Cancer study each took approximately 1 - 1.5 hours to administer and collected information on a large number of exposures including pregnancy history, contraceptive and hormone use, family history of cancer, medical history, psychosocial factors and lifestyle factors. Data were collected on factors that were expected to be associated with increased risk (e.g., family history of cancer, history of infertility, menopausal hormone use, talc use) as well as those expected to be associated with decreased risk (e.g., oral contraceptive use, pregnancies, physical activity). Given the broad range of hypotheses and the numerous exposures that the cases and controls were queried about and the fact that neither cases nor controls were told in advance of the interview about the specific topics that would be covered, it is unlikely that the women with ovarian cancer would have given more thought to their talc use resulting in substantial systematic over-reporting of talc use among cases. This is supported by studies of other cancers that used empirical data to assess the likely effect of recall bias on relative risk estimates when investigators examined numerous exposures and concluded that recall bias did not consistently lead to increased estimates of the relative risk.¹⁴²⁻¹⁴⁴

Further evidence that recall bias in case-control studies does not inevitably lead to an overestimate of the association between a risk factor and exposure comes from a recent review of meta-analyses of observational studies by Lanza et al.¹⁴⁵ This review analyzed a random

sample of 23 meta-analyses of observational studies addressing different exposure/disease associations published in 2013 and compared findings from case-control studies and cohort studies within individual meta-analyses to determine if conclusions from case-control studies were significantly different from those from cohort studies. The authors concluded that there was no significant difference in effect estimates between the case-control and cohort studies, suggesting that the study design did not have an important impact on the conclusions of the meta-analyses. Although recall bias *theoretically* could lead to an overestimate of the association between a risk factor and disease, the empirical evidence indicates that in practice the effect is small in most situations.

The third situation of the effect of media attention on an exposure deserves consideration as there has been reporting in the lay press in recent years about lawsuits involving talc and ovarian cancer. This concern is not relevant to the vast majority of the studies as virtually all of the data collection in the epidemiologic studies of talc and ovarian cancer occurred prior to such litigation. However one notable exception is AACES,¹³ which began enrollment in 2010 and included data collected up through August, 2015. At the recommendation of the reviewer who critiqued the manuscript when it was submitted for publication, our group examined the association between talc and ovarian cancer stratified by the date of enrollment. The odds ratio for genital talc use and ovarian cancer was 1.44 for the overall study population and 1.19 for the participants interviewed before 2014. These data do give some credence to the idea that recall bias could have led to the higher odds ratios when including women interviewed during the time when there was more media attention focused on this exposure, however the fact that the association was attenuated but not eliminated when considering the full study population suggests that the association is not due entirely to recall bias.

Another way to approach the issue of whether recall bias is a likely explanation for the association between talc use and ovarian cancer is to consider whether the association was observed for other gynecologic cancers. The data are admittedly very sparse in this regard, however the only published case-control study of talc use and endometrial cancer reported an odds ratio of 0.88 (95% CI 0.68 – 1.14).⁶⁷ A study of ovarian cancer that was conducted by

several of the same investigators as the endometrial cancer study used similar methodology, was conducted in a similar timeframe (early to mid-2000s) in the same geographic region (Australia) and reported a similar prevalence of talc use in the study population. In contrast to their endometrial cancer study in which the investigators observed a non-significant inverse association with talc use, the investigators found a statistically significant increased risk for ovarian cancer associated with talc use (odds ratio=1.17, 95% CI 1.01 – 1.36).¹²³ While this comparison clearly needs to be interpreted cautiously because there is only a single published case-control study of talc use and endometrial cancer, it does provide evidence to suggest that the association between talc and ovarian cancer observed in most case-control studies is not due simply to recall bias.

Cohort Studies – Strengths and Weaknesses: In contrast to the case-control study, the prospective cohort study design is less susceptible to the selection bias and recall bias described above. Women who develop cancer and the comparison group are from the same population (the cohort) so the bias that could arise from improperly selecting a control group is minimized. Similarly, because the exposure information is collected before the diagnosis of cancer, one would not expect that recall of exposures would differ between the women who went on to develop cancer and those who remained free of cancer.

Despite these advantages, cohort studies do have some important disadvantages in relation to studying cancer etiology. The first is that even with large cohorts, it takes many years for a reasonable number of cancers to develop within the cohort, especially for an uncommon cancer like ovarian cancer. When considering the statistical power of a study to assess the association between an exposure and a disease, the size of the cohort is not the only driver of study power. A more critical consideration is the number of cases that develop within the cohort, which in turn is dependent on the length of follow-up of the larger cohort. Therefore, a large cohort with a relatively short duration of follow-up during which time a small number of cases developed among cohort will have low statistical power. In contrast, the total sample size of a case-control study is likely to be much smaller than a cohort study, but if it has a larger number of cases, it will have greater statistical power than the cohort study.

Among the three cohort studies included in the most recent meta-analysis,⁵⁶ the Nurses' Health Study reported 307 cases in a cohort of 78,630 women after approximately 14 years of follow-up,^{34,146} the Women's Health Initiative reported 429 cases in a cohort of 61,576 women after a mean of 12.4 years of follow-up²⁷ and the Sister Study reported 154 cases in a cohort of 41,654 women after a mean of 6.6 years of follow-up.²⁴ Even with tens of thousands of women in these studies, the number of ovarian cancer cases within each cohort is smaller than the number of ovarian cancer cases in many of the case-control studies. In particular, the number of cases within the Sister Study is smaller than the number of cases in any of the case-control studies published since 1993. As described in a commentary by Narod⁸¹, the lack of a significant overall association between ever use of talc and ovarian cancer in the cohort studies may be due to the fact that despite the large size of the cohorts, the studies were not adequately powered to detect a relative risk of approximately 1.2.

Another limitation of cohort studies that is of greater relevance to the question of talc use and ovarian cancer is information bias related to exposure assessment. Cohort studies are typically designed to examine many different outcomes that develop within the study population over time. The Nurses' Health Study (<http://www.nurseshealthstudy.org/selected-publications>) and Women's Health Initiative (<https://www.nhlbi.nih.gov/whi/references.htm>) have reported on many different outcomes including, but not limited to, multiple types of cancer, cardiovascular diseases, fractures, gastrointestinal conditions and mental health. In contrast, case-control studies focus on a single disease, such as ovarian cancer. Because cohort studies are designed to examine diverse outcomes, the questionnaires must obtain data on risk factors that are relevant to a wider variety of diseases. To keep the questionnaire to a manageable length, a cohort study will typically query about more risk factors but in less detail than a case-control study that is focused on a single disease. This is the case with the talc questions, with the cohort studies collecting less detailed information on talc use, especially in regard to duration and frequency of use, than most of the case-control studies.

It is also worth noting that cohort studies are also subject to recall errors, especially when assessing exposures that began early in life. When the cohort studies assessed talc use, they were asking women to recall their past use of the products up to the point of interview,

similar to how exposure is assessed in the case-control studies. In the Nurses' Health Study, the cohort members were aged 36 to 61 at the time talc use was assessed in 1982, and in the Women's Health Initiative, the mean age at enrollment was 63. Because many women initiate use of talc at a young age, the study participants would have been recalling exposures over several decades, and it stands to reason that there would be some errors in recall. Therefore, in cohort studies as in case-control studies, reported talc use was subject to some degree of inaccurate recall. This likely resulted in non-differential misclassification of the exposure, which usually results in an underestimate of the true relative risk.

Another concern with exposure assessment in cohort studies that is highly relevant to the question of talc use in relation to ovarian cancer is that risk factor information can change over time. If the questionnaire data that were collected when the cohort was assembled do not include a comprehensive exposure history to that time point and are not updated over time, the information may not reflect the complete exposure history of an individual in the time before she was diagnosed with cancer. This could result in some talc users being incorrectly identified as non-users or in incorrect estimates of the duration of exposure.

Incomplete exposure assessment is a potential problem for each of the three cohort studies that have reported on talc use and ovarian cancer, however it is a particular issue for the Sister Study²⁴ which reported a non-significant inverse association between talc use and ovarian cancer (relative risk of 0.73, 95% CI 0.44 – 1.20). Each of the cohort studies assessed talc use at a single point in time and did not update the information at subsequent follow-up interviews. The Nurses' Health Study collected limited information on talc exposure in 1982, and did not collect additional data on talc use in subsequent questionnaires between 1982 and when the results were described in papers published in 2000³⁴ and 2010.¹⁴⁶ Similarly, the Women's Health Initiative collected information on talc exposure when the women were enrolled into the study and did not obtain updated information during the years the cohort was followed. Therefore, any use of talc after that single exposure assessment was not captured, and there would be a certain amount of misclassification of the exposure in both the women who subsequently developed ovarian cancer and those who did not. If the misclassification was non-differential, meaning that the degree of misclassification was similar between the women

who developed ovarian cancer and those who did not, the predicted effect would be a bias towards the null.¹⁴⁰ In other words, non-differential misclassification of talc exposure (as a dichotomous variable) would mean that the observed relative risk was not as strong as it would have been if there had been not misclassification.

The degree of misclassification of exposure in the Sister Study²⁴ is apparently much greater than in the other cohort studies. Use of talc was assessed through questions about personal care products used only in the 12 months prior to enrollment, including genital talc use in the form of powder or spray applied to a sanitary napkin, underwear, diaphragm, cervical cap or vaginal area. This assessment is essentially a “snapshot” of talc use during a short period of time, capturing neither the cumulative use of talc up to that point nor any subsequent use of talc after the baseline interview. Not surprisingly, the reported prevalence of talc use was quite low in this study. The 14% prevalence reported in the Sister Study was markedly lower than the other two cohort studies (40.2% in the Nurses’ Health Study³⁴ and 52.6% in the Women’s Health Initiative²⁷) as well as in nearly all of the case-control studies. In addition to underestimating the prevalence of talc use in their population, their assessment of talc only during the year prior to enrollment probably did not capture exposure during the most relevant period of the woman’s life. As the authors acknowledged in their paper, if latency (the time between exposure and diagnosis of cancer) is 15 to 20 years, the exposure assessments do not accurately reflect the period of risk. The limitations in the assessment of talc use raise serious questions about the validity of the findings from the Sister Study for this particular exposure. It is impossible to predict the direction or the magnitude of the association between talc use and ovarian cancer if the Sister Study had conducted a more complete assessment of the exposure.

A further limitation of the exposure assessment in the Nurses’ Health Study and Women’s Health Initiative is that neither assessed both the frequency and duration of use of talc. This additional limitation has ramifications for assessing dose-response gradients, which will be discussed in a later section of this report.

While cohort studies are often considered a stronger study design for assessing causal relationships between an exposure and outcome, this is not absolutely true for all exposures and outcomes. Rather than making a judgement about the quality of evidence based solely on

study design, it is important to consider study design from a more nuanced perspective and consider whether a cohort or case-control study provides the most optimal assessment of the exposure and outcome. As described above, each of the three cohort studies that has addressed talc use and ovarian cancer risk had substantial limitations in their assessment of talc use within their study population, which weakens their conclusions that talc use is not significantly associated with ovarian cancer risk.

In addition, the Sister Study,²⁴ which is a study that was designed primarily to examine breast cancer outcomes among women who had a sister with breast cancer, the small number of ovarian cancer cases despite the large size of the cohort and the inadequate assessment of talc exposure arguably make it a much weaker study than some of the larger, well-designed population-based, case-control studies. Notably, this study, with a relative risk estimate of 0.73 (95% CI 0.44 – 1.20)²⁴ could be considered an outlier as it is only one of two studies that reported a relative risk substantially less than 1, the other being Hartge's 1983 hospital-based case-control study.⁴⁹

Uncontrolled Confounding in Observational Studies: Uncontrolled confounding is a potential concern in both case-control and cohort studies since they are observational studies. If a factor is associated with talc use *and* is a risk factor for ovarian cancer and is not accounted for in the statistical analysis, it could confound the association between talc use and ovarian cancer. In other words, if there is confounding, the increased risk observed with talc use could be due to the failure to account for the other risk factor. Vaginal douching, which was found to be associated with ovarian cancer risk in the Sister Study, was examined as a potential confounder of the association between talc use and ovarian cancer.²⁴ Their analyses showed that adjusting for douching using statistical modelling had a negligible effect on the association between talc use and ovarian cancer, providing no evidence of confounding. Other studies have either found an association between talc and ovarian cancer when controlling for douching⁴⁴ or found no association between douching and ovarian cancer,⁴⁹ thus the available data do not support that douching is a confounder of the association between talc and ovarian cancer. Although uncontrolled confounding is a theoretical possibility, to my knowledge, in the more

than 30 years of research on talc and ovarian cancer no such confounder has been identified that could account for the increased risk associated with talc use.

Overall, the meta-analyses indicate a high level of consistency in findings, especially from the case-control studies. Although weaker associations were observed in the cohort studies, the most recent meta-analysis did report statistically significant associations with invasive serous ovarian cancer in the cohort studies as well as in the case-control studies that reported on histologic subtype.⁵⁶ As a whole, the weaker associations observed for the cohort studies could be plausibly explained by limited methods used for talc exposure assessment, the limitations described above, including the most recent cohort study by Gonzalez, et al.,²⁴ which will have the predicted effect of biasing the results towards the null (i.e., showing an effect that is weaker than the true effect).

Taken as a whole, the overwhelming statistical strength of these studies, whose results are replicated over decades across a wide variety of populations and investigators, further supported by consistent meta-analysis, weighs very heavily in favor of a causal inference.

Temporality

Temporality is the only consideration that is an absolute criterion when making a judgment of causality. This criterion states that a cause (the exposure) must precede the effect (the outcome of interest) in time. Both the cohort and case-control studies that examined talc use in relation to ovarian cancer assessed talc exposure that preceded the diagnosis. In cohort studies, the questionnaire data are obtained before any women in the cohort have a diagnosis of ovarian cancer, and in the case-control studies, women with ovarian cancer are asked to report on exposures that occurred before their diagnosis and controls are asked to report on exposures that occurred in a similar time frame. Therefore, there is no question that the exposure assessment captured talc exposure that preceded the diagnosis of ovarian cancer. Nevertheless, this factor is not highly weighted; while its absence would be fatal to a causal inference, its presence is not particularly compelling support for causation.

Biological Gradient

Associations that show evidence of a biological gradient, or dose-response relationship, are considered to have stronger evidence of causality. While the inconsistencies in reported dose-response trends for talc and ovarian cancer have been noted in some meta-analyses and reviews, e.g.,^{51,54} there are several considerations about this exposure that should be taken into account.

First, for an association like talc and ovarian cancer, the dose that is most relevant is the amount of talc that actually reaches the fallopian tubes and ovaries. The epidemiologic data rely on measures of external application as a surrogate of the level of exposure, not the actual exposure in the upper genital tract.

Second, there is some inherent inaccuracy in the measurement of the exposure, as the participants in most studies were asked to recall their duration and/or frequency of use over many years.

Third, the dose of talc exposure has been assessed differently across the studies. Some studies assessed only duration of use (months or years), some assessed only frequency of use (e.g., number of days per month) and some used measures of both duration and frequency to come up with a measure of total dose (estimated lifetime number of applications). The limitations of relying on duration or frequency alone as a measure of talc dose are apparent. For certain exposures, oral contraceptive use for example, duration of use is a good measure of total exposure because the pills are taken once daily. In contrast, patterns of talc exposure may be more inconsistent. Some women may use it daily, others only during their menstrual periods, others may apply it only during certain times of the year and others may have still different patterns of use. Measures of exposure based only on duration of use or only on frequency of use could result in inaccurate estimates of total exposure and obscure a dose-response relationship.

Some of the meta-analyses have cited the lack of a clear dose-response relationship as an argument against talc being a cause of ovarian cancer, and when considering measures of either years of talc use or number of applications of talc per month, there is considerable heterogeneity across studies. When considering the studies that examined dose-response associations considering both dose and frequency to estimate the total number of applications

of talc,^{13,14,25,29,30,32,35,41}, the majority^{13,14,25,30,32} did find significant trends of higher risk with more lifetime applications of talc.

Terry, et al.¹⁴ noted in the pooled analysis of eight case-control studies that the trend for increasing risk for non-mucinous ovarian cancers with an increasing number of genital powder applications was significant when non-users were included in the analysis, but the trend was not significant when the analysis was restricted to ever users. The authors therefore concluded that the significant trend was largely due to the comparison of women who had ever used talc versus those who had never used it, suggesting that the dose-response relationship was not a simple linear increase in risk with greater exposure to talc.

While there is evidence of a dose response relationship in the majority of the studies that considered both frequency and duration of use (i.e., total number of applications), these observations are less consistent than the overall association between talc and ovarian cancer. There are several possible reasons why not all studies observed dose-response relationships, even when an overall association was observed in the study. First, there is likely to be greater inaccuracy in the recall of duration of use as compared to ever/never use, which would tend to obscure a dose-response relationship. Second, when “ever-users” were stratified into duration of use categories, it often resulted in strata with small numbers of women, resulting in less stable relative risk estimates within the duration categories. Third, as noted by Terry, et al.¹⁴, the dose-response relationship may not be a simple linear trend. In many of the studies, even the women in the lowest exposed category had hundreds of episode of talc exposure. Because there could have been considerable exposure even among the women in the “low” exposure categories, greater exposure may not have resulted in substantially increased risk and thus a linear trend may not have been apparent.

Overall, biological gradient was given lesser weight in my assessment of the literature, based on: 1) some of the studies that assessed a dose-response relationship evaluated only duration or frequency of use and not total number of applications, 2) duration and frequency of use are subject to more misclassification than ever use of talc, 3) small sample sizes within strata lead to unstable estimates, and 4) there is the possibility of a non-linear dose-response relationship. Nonetheless, even with these limitations, there was still evidence of a dose-

response relationship in the majority of studies that evaluated it based on the total number of applications.

Biologic Plausibility

Biological plausibility refers to whether there is a reasonable biological mechanism through which the exposure could lead to the disease. Hill is quick to point out that biological plausibility depends on the current state of scientific knowledge. Specifically, Hill wrote “It will be helpful if the causation we suspect is biologically plausible. But this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day.” It is clear that from these statements that the consideration of biological plausibility does not require that there is a *proven* biological mechanism to make a judgment of causality between an exposure and disease. Therefore, for this Hill consideration, a scientist looks for biological evidence that might explain the associations that are observed in the epidemiologic studies. In other words, one has to see whether the observed association “makes sense” biologically. In this case, I have considered both clinical plausibility and biological plausibility. Both of these show that the association seen in the epidemiologic studies “makes sense.”

It is probably safe to say that our understanding of the complex biological processes that lead from exposure to disease is incomplete for all cancers. In some instances, the precise biological mechanisms by which an exposure leads to disease remain unclear and in others, some mechanisms are well-established but there is not a complete understanding of why some exposed individuals develop the disease and others do not. An example of the former is alcohol consumption as a cause of breast cancer. While alcohol is considered by IARC to be an established cause of breast cancer,¹²⁸ recent publications still describe the association as one in which the exact biological pathways are unclear, even though several possible mechanisms have been hypothesized (i.e., metabolism to acetaldehyde or effects on estrogen levels).^{147,148} An example of the latter is smoking and lung cancer. Mechanisms of carcinogenesis from constituents of tobacco smoke have been well-described,¹⁴⁹ however it remains unclear as to why some smokers are more susceptible to developing lung cancer. In short, it is important to

recognize that biological plausibility depends on the current state of knowledge and may evolve over time as new evidence emerges.

When considering the likelihood of talcum powder products causing ovarian cancer, there is robust data that leads to the conclusion that there are biologically plausible mechanisms by which this exposure could lead to ovarian cancer. Specifically, 1) talcum powder products can migrate from the perineum through the genital tract to the ovaries and fallopian tubes, 2) talcum powder products can become imbedded in the ovarian tissue; 3) talcum powder products can induce an inflammatory response, and 4) the inflammatory response can result in increased oxidative stress and expression of cytokines, mutagenesis, and cell proliferation.

Pathology studies have demonstrated that particles may ascend the female genital tract from the vagina to the fallopian tubes and ovaries,^{150,151} and talc particles have been identified in ovarian tissue.^{71,76,78,79} In fact, the FDA's 2014 response to the Citizen's Petition requesting a cancer warning label on cosmetic talc products states that "the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable".¹⁵² Therefore, it is highly plausible that application of talcum powder products to the genital area can result in exposure to the ovaries.

It is also plausible that inhalation of talc products could also be a route of exposure leading to cancer. Studies of asbestos exposure indicate that inhalation of asbestos fibers can result in exposures to the peritoneal tissue, through transport through the lymphatic system and/or blood.¹⁵³⁻¹⁵⁵ There is strong evidence that such exposure can result in cancer, most notably mesothelioma. Inhalation of talcum powder products could result in similar peritoneal exposure.

Given the evidence that external application of talcum powder products can reach the ovaries either through upward migration through the genital tract or through inhalation and subsequent transport through the lymphatic system and/or blood, there are plausible biological pathways by which talc could lead to the development of ovarian cancer.

It is well-established through several lines of evidence that talc can cause inflammation. The inflammatory properties of talc are exploited for clinical use in talc pleurodesis, a treatment

for malignant pleural effusions or pneumothorax that involves instillation of talc into the pleural space.^(<https://www.uptodate.com/contents/talc-pleurodesis>) The resultant inflammation and fibrosis result in adhesion of the layers of the pleura, closing the pleural space. The inflammatory properties of talc are also evident in that chronic or acute exposure to talc through inhalation which can result in pulmonary talcosis, a chronic inflammation of the lower respiratory tract.^{156,157} Animal studies also confirm that talc causes inflammation, as experiments in rats treated with intra-vaginal or perineal talc showed inflammatory changes in the genital tract.⁷⁰ Although neoplastic changes were not observed in this experiment, this could be explained by the small number of animals (n=7) in each group or the duration of the experiment (3 months).

Inflammation has been identified as one of the hallmarks of cancer, with both extrinsic and intrinsic pathways described.^{158,159} Talc would be characterized as being involved in an extrinsic pathway, in which an exposure or condition results in chronic, non-resolving inflammatory responses. Chronic inflammation can lead to a cascade of cellular events that could result in damage to DNA, increased cell division and generation of inflammatory mediators.

Recent work by Saed, Fletcher, et al.^{160,161} describes the role of oxidative stress in the pathogenesis of ovarian cancer and the effects of talc on the oxidative state of ovarian cancer cell lines. Oxidative stress results when the balance between oxidant and anti-oxidant enzymes and molecules in cells is altered, resulting in an excess of reactive oxygen species or reactive nitrogen species. Oxidative stress, which can result from numerous factors including exposure to carcinogens, infection and chronic inflammation, has been shown to affect the initiation, promotion and progression of several types of cancer. Saed, et al. have reported that talc can generate a pro-oxidant state in both normal ovarian epithelial cells and ovarian cancer cells. Exposure to talc resulted in an increase in mRNA levels of certain pro-oxidant enzymes and a decrease in the mRNA of several anti-oxidant enzymes, suggesting a possible cellular mechanism by which exposure to talc could contribute to the development of ovarian cancer.

There is also evidence in the medical literature that talc products contain additional constituents that are known ovarian carcinogens, particularly asbestos.¹⁶²⁻¹⁶⁶

Asbestos is one of the most established carcinogens in our environment, and is associated with a variety of cancers including mesothelioma, lung, larynx and ovarian.^{167,168} IARC has stated that “a causal association between exposure to asbestos and cancer of the ovary was clearly established,” based on strongly positive cohort mortality studies of women with occupational exposure to asbestos as well as studies of women with environmental exposure to asbestos.¹⁶⁹ The Occupational Safety and Health Administration has stated that “there is no safe level of asbestos exposure for any type of asbestos fiber” and that asbestos exposures as short as a few days have resulted in cancer (mesothelioma), indicating that even low levels of exposure may be carcinogenic. (<https://www.osha.gov/SLTC/asbestos/>)

Although it has been often stated that talc products manufactured after 1976 are asbestos-free, evidence from published scientific reports,^{57,162} analyses performed on samples manufactured and packaged at different time points after 1976,¹⁷⁰⁻¹⁷³ and internal documents and testimony from the defendants demonstrate that statement is inaccurate.^{174,175} There is evidence that products manufactured after 1976 are not asbestos-free. Studies from Longo, et al. show that talc products can contain asbestos and talc containing asbestiform fibers (e.g., talc occurring in a fibrous habit).^{170,171} Therefore it is reasonable to conclude that women who regularly used talc products, both before and after 1976, were likely exposed to asbestos and talc containing asbestiform fibers through their use of these products.

Analyses of talcum powder products also demonstrate the presence of other constituents such as chromium and nickel which are well established carcinogens, and cobalt which is considered a possible carcinogen.^{169,174} I have also reviewed a report analyzing the 150+ known fragrance ingredients in talcum powder products, many of which have been determined harmful to humans.¹⁷⁶ The presence of these substances provide further evidence that exposure to talc products could result in cancer

It is also plausible that even among women recently diagnosed with ovarian cancer, exposure to the pre-1976 talc products, which are generally understood to have contained asbestos and talc containing asbestiform fibers, increased their risk for ovarian cancer. It is well-established that many cancer risk factors have a long latency, which the National Cancer Institute defines as “the time that passes between being exposed to something that can cause

disease and having symptoms”. Numerous examples of cancer risk factors with prolonged latency periods exist. For example, lung cancer typically is not diagnosed among cigarette smokers for several decades after initial exposure¹⁷⁷ and having severe sunburns during childhood is a risk factor for melanoma,¹⁷⁸ which has a median age of diagnosis of 63 years.¹³⁵

It has also been reported that the latency period between exposure to asbestos and mesothelioma (the cancer most strongly linked to asbestos exposure), ranges from 15 to more than 70 years.^{179,180} The median latency has been estimated at 22 to 32 years, with longer latency periods estimated for women than for men.^{179,180} Thus, it is not unreasonable to conclude that exposure to talc products early in a woman’s life could result in ovarian cancer decades later.

Further, other established risk factors for ovarian cancer also demonstrate long latency periods. Oral contraceptive use and history of pregnancy are two of the factors that are most consistently reported in association with ovarian cancer (both of which reduce risk). Although, these are “exposures” that typically occur when women are in their teens, twenties or thirties, the median age of diagnosis of ovarian cancer is 61 years, suggesting that events and exposures from early in a woman’s reproductive life can influence her risk for ovarian cancer decades later.

The totality of this evidence indicates that there are plausible biological pathways by which use of talc products could lead to ovarian cancer. There is clear evidence that external applications of these products can result in exposure to the ovaries, through upward migration through the genital tract or inhalation exposure. Once exposed, there are plausible biological mechanisms, by which talc itself or constituents of the talcum powder product could lead to carcinogenic transformation of ovarian cells. This includes credible evidence that talc products contain asbestos fibers, a known ovarian carcinogen, regardless of whether they were manufactured before or after 1976. While it is likely that advances in scientific knowledge may further refine our understanding of how talc exposure can lead to ovarian cancer, our current knowledge is adequate to conclude that there are plausible biological pathways leading from talc exposure to ovarian cancer.

I have considered the biologic plausibility that would support and detract from the hypothesis that talcum powder products can cause ovarian cancer. The more persuasive evidence is that talc can migrate to the ovaries through the genital tract and become imbedded in ovarian tissue. It is also plausible that talc could reach the peritoneal cavity through an inhalation route. Regardless of the route of exposure, it is clear that talcum powder products, including constituents like asbestos and fibrous talc, may cause an inflammatory response and oxidative stress that could lead to cell damage. These biologically plausible mechanisms are a persuasive explanation for the consistent increased risk we have observed in the epidemiologic studies. *Simply put, the observed association “makes sense” biologically.* Along with consistency and strength, I considered this a strong factor favoring a causal inference.

Specificity

As described by Hill,¹²¹ if specificity exists between an exposure characteristic and disease, it provides strong evidence of causality. However, he also stated that “one-to-one relationships are not frequent ...multi-causation of disease is generally more likely than single causation”. Clearly, ovarian cancer has multiple causes, with talc exposure among many known risk factors. From the standpoint of there being a “one-to-one relationship” between talc and ovarian cancer, there is not a high level of specificity. However, given that talcum powder products are particularly associated with epithelial ovarian cancer, especially serous ovarian cancer, it does support that it is a fairly specific relationship. This aspect was given only modest weight, because talc is one of many possible causes of ovarian cancer.

Coherence

It is recognized that the plausibility depends on the current state of biological knowledge. Knowledge of the biological mechanisms for ovarian carcinogenesis (and virtually any other disease) is incomplete and will continue to evolve as further research continues. Coherence, as described by Hill, means that, even if the knowledge of biology of the disease is not well-defined, the “data should not seriously conflict with the generally known facts of the natural history and biology of the disease”.¹²¹ Given the current state of knowledge of ovarian

carcinogenesis, the postulated mechanisms by which talc exposure leads to ovarian cancer do not conflict with the current state of knowledge on ovarian carcinogenesis. This aspect was given considerable weight as it is important that the overall evidence fit together in a coherent manner. Taking into account the plausible pathways by which talc products could reach the target tissue, the expected latency period between exposure and disease, and biological mechanisms that are consistent with our knowledge of carcinogenesis, the data are consistent with the natural history and biology of ovarian cancer.

Experiment

As described above, the epidemiologic data on talc use and ovarian cancer are from observational studies, therefore there are no clear cut experimental data on which a causal assessment can be made. Hill acknowledged that experimental data are often not available for the exposure/disease associations under study, but in some circumstances, experimental or semi-experimental evidence is available.¹²¹ For example, if a preventive action is taken to remove the exposure and the incidence of disease declines, there is strong support for a causal relationship. No such experimental evidence is available for talc use and ovarian cancer.

Analogy

The final viewpoint defined by Hill ¹²¹ is analogy, whereby evidence of an association with one risk factor would suggest that a similar risk factor could also plausibly be associated with the disease. Because this viewpoint is rather vague, it is often not incorporated into causal assessments. Nevertheless, while I did not weight it heavily, the similarity between asbestos and asbestiform talc – both of which are widely accepted as causing ovarian cancer – is supportive of this viewpoint.

Conclusion

Epidemiologic evidence linking genital talc use to ovarian cancer has been accruing since 1982.⁵⁰ As I evaluated this evidence, I considered the results from individual studies with different designs (case-control and cohort) as well as meta-analyses and a pooled analysis of

multiple case-control studies. In my evaluation of the data, I considered the strengths and weaknesses of individual studies, recognizing that there are advantages and disadvantages of both case-control and cohort studies for evaluating talc as a risk factor for ovarian cancer. I used the Bradford Hill framework as a guide for making my weight of the evidence assessment of whether there is evidence for a causal association between talc use and ovarian cancer.

The epidemiologic evidence I evaluated was derived from more than two dozen studies conducted in many different settings. The vast majority of studies reported relative risks or odds ratios greater than one, indicating that women with ovarian cancer were more likely to have used talc products than women without ovarian cancer. Meta-analyses, which combine findings across multiple studies to come up with an overall estimate of risk that is more statistically robust, have consistently reported that there is a statistically significant increased risk for ovarian cancer among women who reported genital talc use. While meta-analyses have noted that the relative risk estimates from case-control studies have been larger than from cohort studies, limitations in all of the cohort studies could explain the weaker associations observed in these studies. It is also noteworthy that the most recent meta-analysis⁵⁶ reported significantly increased risks for invasive serous ovarian cancer, which is the most common subtype as well as the one with the worst prognosis, in both cohort and case-control studies.

The epidemiologic studies that have examined talc use in relation to ovarian cancer risk have been conducted in very diverse populations, both within and outside the United States and in women of different race/ethnicities. The consistency of the findings across populations adds credibility to the findings of increased risk of ovarian cancer among talc users.

The relative risk estimates in most studies and the summary relative risk estimates from the meta-analyses are of a magnitude (~1.25-1.30) that is comparable to other common exposures that are causally related to cancer (e.g., passive smoke exposure and lung cancer, oral contraceptive use and breast cancer, menopausal estrogen use and breast cancer, residential radon exposure and lung cancer). Additional evidence supportive of talc being an ovarian cancer risk factor are biologically plausible mechanisms based on inflammation pathways, oxidative stress and the presence of asbestos, asbestiform talc, and other known

carcinogens in talcum powder products. Evidence of a dose-response relationship exists in many of the studies that considered both duration and frequency of exposure.

Based on the evidence in total, it is my opinion with a reasonable degree of scientific certainty that use of talcum powder products can cause ovarian cancer. I reserve the right to modify or refine my opinions based on additional scientific evidence that may emerge on this topic.

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EXHIBIT A

***Duke University Medical Center
Curriculum Vitae***

Date Prepared: October 2018

Patricia Gripka Moorman, M.S.P.H., Ph.D.

Primary academic department: Department of Community and Family Medicine
Duke University Medical Center

Present academic rank and title: Professor with tenure, September 2014

**Date and rank of first Duke
faculty appointment:** July 1, 2000, Assistant Professor

Medical licensure: N/A

Date of birth: December 19, 1957

Place of birth: Kansas City, Kansas, USA

Citizen of: United States of America

EDUCATION

	Institution	Year	Degree
High School	Bishop Ward High School Kansas City, KS	1975	Diploma
College	University of Kansas Lawrence, KS	1980	B.S. with distinction, Pharmacy
Graduate School	University of North Carolina – Chapel Hill Chapel Hill, NC	1989	M.S.P.H., Epidemiology
	University of North Carolina – Chapel Hill Chapel Hill, NC	1993	Ph.D., Epidemiology

PROFESSIONAL TRAINING AND ACADEMIC CAREER

Institution	Position/Title	Dates
Shalinsky Drugs, Kansas City, KS	Pharmacist	1980-1981
Community Pharmacy, Wrentham, MA	Pharmacist, Manager	1981-1982
Revco Drugs, Durham/Raleigh, NC	Pharmacist, Manager	1983-1993
Department of Epidemiology University of North Carolina - Chapel Hill	Graduate Research Assistant Teaching Assistant	1987-1993
Burroughs Wellcome Research Triangle Park, NC	Epidemiology Research Associate Summer Intern	1988
Department of Epidemiology Lineberger Comprehensive Cancer Center University of North Carolina - Chapel Hill	Research Assistant Professor	1994-1996
Dept. of Epidemiology and Public Health Yale Comprehensive Cancer Center Yale University School of Medicine New Haven, CT	Associate Research Scientist	1997-2000
Department of Epidemiology University of North Carolina - Chapel Hill	Adjunct Assistant Professor Adjunct Associate Professor	2000-2005 2005-present
Dept. of Community and Family Medicine Duke University Medical Center	Assistant Professor Associate Professor (non-tenured) Associate Professor (tenured) Professor (tenured) Clinical Research Unit Director (formerly Site-Based Research Director)	2000-2004 2004-2008 2008-2014 2014-present 2009-present

PUBLICATIONS

Refereed Publications

1. Aldrich TE, Vann D, **Moorman PG**, Newman B. Rapid reporting of cancer incidence in a population-based study of breast cancer: one constructive use of a central cancer registry. *Breast Cancer Res Treat.* 1995; 35: 61-64.
2. Newman B, **Moorman PG**, Millikan R, Qaqish BF, Geradts J, Aldrich TE, Liu ET. The Carolina Breast Cancer Study: integrating population-based epidemiology and molecular biology. *Breast Cancer Res Treat.* 1995: 51-60.
3. Newman B, Mu H, Butler L, Millikan RC, **Moorman PG**, King M-C. Frequency of breast cancer attributable to BRCA1 in a population-based series of American women. *JAMA.* 1998; 279: 915-21.

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6. Rockhill B, **Moorman PG**, Newman B. Age at menarche, time to regular cycling, and breast cancer. *Cancer Causes Control*. 1998; 9: 447-53.
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8. Marcus PM, Baird DD, Millikan RC, **Moorman PG**, Qaqish B, Newman B. Adolescent reproductive events and subsequent breast cancer risk. *Am J Public Health*. 1999; 89: 1244-7. (PMCID: PMC1508686)
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12. Hall IJ, Newman B, Millikan RC, **Moorman PG**. Body size and breast cancer risk in black and white women: the Carolina Breast Cancer Study. *Am J Epidemiol*. 2000; 151: 754-64.
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14. Kinney AY, Millikan RC, Lin YH, **Moorman PG**, Newman B. Lifetime alcohol consumption and breast cancer among black and white women in North Carolina. *Cancer Causes Control*, 2000; 11: 345-57.
15. **Moorman PG**, Kuwabara H, Millikan RC, Newman B. Menopausal hormones and breast cancer in a biracial population. *Am J Public Health*. 2000; 90: 966-70. (PMCID: PMC1446270)
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31. Schildkraut JM, Demark-Wahnefried W, Wenham RW, Grubber J, Jeffreys AS, Grambow SC, Marks J, **Moorman PG**, Hoyo C, Ali S, Walther PJ. IGF1 (CA)19 repeat and IGFBP3 -202 A/C genotypes and the risk of prostate cancer in black and white men. *Cancer Epidemiol Biomarkers Prev.* 2005;14: 403-8
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55. Song H, Ramus SJ, Kjaer SK, DiCioccio RA, Chenevix-Trench G, Pearce CL, Hogdall E, Whittemore AS, McGuire V, Hogdall C, Blaakaer J, Wu AH, Van Den Berg DJ, Stram DO, Menon U, Gentry-Maharaj A, Jacobs IJ, Webb PM, Beesley J, Chen X; Australian Cancer (Ovarian) Study; Australian Ovarian Cancer Study Group, Rossing MA, Doherty JA, Chang-Claude J, Wang-Gohrke S, Goodman MT, Lurie G, Thompson PJ, Carney ME, Ness RB, Moysich K, Goode EL, Vierkant RA, Cunningham JM, Anderson S, Schildkraut JM, Berchuck A, Iversen ES, **Moorman PG**, Garcia-Closas M, Chanock S, Lissowska J, Brinton L, Anton-Culver H, Ziogas A, Brewster WR, Ponder BA, Easton DF, Gayther SA, Pharoah PD; Ovarian Cancer Association Consortium (OCAC). Association between invasive ovarian cancer susceptibility and 11 best candidate SNPs from breast cancer genome-wide association study. *Hum Mol Genet.* 2009; 18: 2297-304. (PMCID: PMC2685754)
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case-control study with three groups of controls. *Cancer Epidemiol Biomarkers Prev.* 2009; 18:1232-8. (PMCID: PMC2700947)

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Letters

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Book Chapters and Invited Papers

1. **Moorman PG**, Hames CG, Tyroler HA. Socioeconomic status and morbidity and mortality in hypertensive blacks. In Brest AN and Saunders E (eds): *Cardiovascular Clinics: Cardiovascular Diseases in Blacks*. FA Davis Company, Philadelphia, 1991, 179-93.
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4. **Moorman PG**, Terry PD. Dairy products and breast cancer. 2003. United Kingdom Dairy Council. (Invited paper)
5. **Moorman PG**, Berchuck A. Comment on: Hormone replacement therapy does not increase risk for ovarian cancer in women with BRCA mutations. *North American Menopause Society First to Know*. Feb. 15, 2006. www.menopause.org/news.html.
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8. **Moorman PG**. Ovarian failure after pre-menopausal hysterectomy. *European Obstetrics & Gynecology*. 2012; 7: 35-8. (Invited paper)
9. **Moorman PG**. Genetic markers for ovarian cancer risk: are we close to seeing a clinical impact? *Personalized Medicine*. 2012; 9: 565-7. (Invited paper)
10. **Moorman PG**. Should women at high risk for cancer use oral contraceptive pills? *Personalized Medicine*. 2015, 12: 533-5. (Invited paper)

Technical Reports

1. **Moorman PG**, Goldstein K, Coeytaux R, Myers ER, Strauss J, Van Houtven C, Shepherd-Banigan M, Brancu M, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Sanders-Schmidler G. Topic Brief: Nutritional needs of older women. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.
2. Myers ER, Strauss J, Van Houtven C, Goldstein K, Shepherd-Banigan M, Brancu M, **Moorman PG**, Coeytaux R, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Sanders-Schmidler G. Topic Brief: Maternal Health. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.
3. Strauss J, Brancu M, Myers ER, Anderson S, Van Houtven C, Goldstein K, Shepherd-Banigan M, **Moorman PG**, Coeytaux R, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Sanders-Schmidler G. Topic Brief: Women's Mental Health. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.

4. Goldstein K, Coeytaux R, Myers ER, Strauss J, Van Houtven C, Shepherd-Banigan M, Brancu M, **Moorman PG**, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Sanders-Schmidler G. Topic Brief: Girls' Health and Obesity. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.
5. Shepherd-Banigan M, Van Houtven C, Brancu M, Goldstein K, **Moorman PG**, Strauss J, Coeytaux R, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Myers ER, Sanders-Schmidler G. Topic Brief: Family Caregivers for Older Adults. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.

Non-authored Publications (acknowledged for contributions)

1. Newman B, Millikan RC, King M-C. Genetic epidemiology of breast and ovarian cancers. *Epidemiol Rev.* 1997; 19: 69-79.
2. Millikan R, Pittman G, Tse C-K, Savitz DA, Newman B, Bell D. Glutathione S-transferases M1, Ti, and P1 and breast cancer. *Cancer Epidemiol Biomarkers Prev.* 2000; 9: 567-73.
3. Krajcik RA, Massardo S, Orentreich N. No association between serum levels of tumor necrosis factor- α (TNF- α) or the soluble receptors sTNFR1 and sTNFR2 and breast cancer risk. *Cancer Epidemiol Biomarkers Prev.* 2003; 12: 945-6.
4. Trivers KF, Stewart SL, Peipins L, Rim SH, White MC. Expanding the public health research agenda for ovarian cancer. *J Womens Health.* 2009; 18: 1299-305.
5. Soubry A, Il'yasova D, Sedjo R, Wang F, Byers T, Rosen C, Yashin A, Ukrantseva S, Haffner S, D'Agostino R Jr. Increase in circulating levels of IGF-1 and IGF-1/IGFBP-3 molar ratio over a decade is associated with colorectal adenomatous polyps. *Int J Cancer.* 2012; 131: 512-7.

Presentations and Published Abstracts (selected)

Moorman PG, Newman B, Butler LM, Ostermeyer EA, Friedman LS, Millikan RC, Liu ET, King MC. Inherited susceptibility at BRCA1 in a population-based sample. Society for Epidemiologic Research, Boston, MA, June 1996

Rockhill B, Newman B, **Moorman P**, Millikan R, Weinberg C. Summary attributable fraction and breast cancer risk factors. Society for Epidemiologic Research, Boston, MA, June 1996.

Furberg H, Newman B, **Moorman P**, Millikan R. Lactation and breast cancer risk. Society for Epidemiologic Research, Edmonton, Alberta, Canada, June 1997.

Marcus PM, Newman B, Millikan RC, **Moorman PG**, Baird DD, Sternfeld B, Qaqish B. The association of adolescent body mass index (BMI) and physical activity with breast cancer risk. Society for Epidemiologic Research, Edmonton, Alberta, Canada, June 1997.

Huang WY, Newman B, Millikan RC, Schell MJ, **Moorman PG**. Hormone-related factors and risk of breast cancer by estrogen receptor and progesterone receptor status. Society for Epidemiologic Research, Chicago, MD, 1998.

Hall IJ, Newman B, Millikan RC, **Moorman PG**. Evaluating body size and breast cancer risk among black women. Society for Epidemiologic Research, Chicago, MD, 1998.

Marcus PM, Newman B, Millikan RC, Baird DD, **Moorman PG**, Qaqish B. Breast cancer epidemiology: the case for adolescent exposures. Society for Epidemiologic Research, Baltimore, MD, 1999.

Moorman PG. Menopausal hormones and risk of breast cancer. Carolina Breast Cancer Study Participant Symposium, Chapel Hill, NC, April 2000

Moorman PG, Jones BA, Millikan RC, Hall IJ, Newman B. Race, anthropometric factors, and stage at diagnosis of breast cancer. Society for Epidemiologic Research, Seattle, WA, June 2000.

Hall IJ, Newman B, Millikan RC, **Moorman PG**. Comparative analysis of breast cancer risk factors among African-American women and white women. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001.

Moorman PG, et al. Nuts and bolts of field studies: things they didn't teach you in school. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001. (Invited talk)

Moorman PG, Calingaert B, Vine M, Halabi S, Berchuck A, Schildkraut JM. Comparison of two methods for calculating lifetime ovulatory cycles. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001.

Plummer P, Jackson S, Konarski J, Mahanna E, Dunmore C, Regan G, Mattingly D, Parker B, Williams S, Andrews C, Vannappagari V, Hall S, Deming S, Hodgson E, **Moorman P**, Newman B, Millikan R. Making epidemiologic studies responsive to the needs of participants and communities: the Carolina Breast Cancer Study experience. Conference on Breast Cancer and Environmental Mutagens, Research Triangle Park, NC, September 2001.

Moorman PG. Population-based study of breast cancer among African-American and White women in North Carolina. North Carolina Central University, Durham, NC, January 2003. (Invited talk)

Moorman PG. Medication use and breast cancer risk. Psychiatry and Behavioral Sciences Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY, March 2003. (Invited talk)

Sansbury L, Millikan R, Schroeder J, **Moorman P**, North K, Sandler R. Use of non-steroidal anti-inflammatory drugs, cyclooxygenase-2 Val411Ala polymorphism and association with colon cancer in a population-based study of African Americans and whites. 3rd Annual AACR International Conference, Seattle, WA, October 2004.

Schildkraut JM, Berchuck A, Murphy S, Marks J, **Moorman P**, Calingaert B, Halabi S. Trinucleotide repeat polymorphisms in the androgen receptor gene and risk of ovarian cancer. 3rd Annual AACR International Conference, Seattle, WA, October 2004.

Moorman PG, Sesay J, Nwosu V, Millikan R. Non-steroidal anti-inflammatory drugs, COX2 polymorphism and breast cancer: a study of gene-environment interactions. Triangle Cancer and Disparities Symposium, North Carolina Central University, Durham, NC, March 2005.

Moorman PG. Racial disparities in breast cancer: problem or opportunity? Johnson C. Smith University, Charlotte, NC, September 2005. (Invited talk)

Trivers K, Gammon M, Abrahamson P, Lund MJ, Kaufman J, **Moorman P**, Cai JW, Porter P, Brinton L, Eley JW. Reproductive factors and breast cancer survival in women less than 55 years of age. 4th Annual Conference on Frontiers in Cancer Prevention Research, Baltimore, MD, November 2005.

Moorman PG. The role of epidemiology in the drug development process. University of Ferrara, Ferrara, Italy, May 2006. (Invited talk)

Moorman PG. Racial disparities in breast cancer: risk factors through survival. Women's Health Research Symposium - Untying the Pink Ribbon: Advances in Breast Cancer. University of Maryland School of Medicine. Baltimore, MD, March 2008. (Invited talk)

Moorman PG, JM Schildkraut JM, ES Iversen ES, ER Myers ER, M Gradison M1, N Warren-White N, F Wang. Weight gain after pre-menopausal hysterectomy. Society for Epidemiologic Research, Chicago, IL, June 2008.

Moorman PG. Non-steroidal anti-inflammatory drugs (NSAIDs) as chemopreventives for cancer: are they ready for prime time? Genetics and Environmental Mutagenesis Society 26th Annual Fall Meeting. Research Triangle Park, NC, October 2008. (Invited talk)

Moorman PG. Introduction to cancer epidemiology. Osher Lifelong Learning Institute lecture series. Chapel Hill, NC, September 2009. (Invited talk)

Moorman PG. Challenges of epidemiologic research in the genomic era: the example of ovarian cancer. Environmental Mutagen Society Annual Meeting, St. Louis, MO, October 2009 (Invited talk)

Moorman PG. Epidemiology in clinical research: beyond randomized controlled trials. Duke University Health System Clinical Education and Professional Development Series, Durham, NC, January 2010. (Invited talk)

Moorman PG. Epidemiology in clinical research: beyond randomized controlled trials. Association of Clinical Research Professionals, Durham, NC, June 2010. (Invited talk)

Moorman PG. The role of epidemiology in understanding disparities in breast cancer. Duke Oncology Symposium – Advances in Surgical and Treatment Options for Breast and Colorectal Cancer. Raleigh, NC, May 2011. (Invited talk)

Østbye T, **Moorman P.** Measurement dilemmas: validity, reliability and messy data. Family Medicine Research Seminar Series, Duke University Medical Center, December 2011.

Moorman P, Østbye T. Research that can tell you something: internal and external validity in study design. Family Medicine Research Seminar Series, Duke University Medical Center, November 2011.

Myers ER, Havrilesky LJ, Gierisch J, **Moorman PG**, Dinan MA, Coeytaux R, Urrutia RP, Lowery WJ, Hasselblad V, McBroom AJ, Sanders GD. Using net benefits and acceptability curves to quantify uncertainty about tradeoffs between harms and benefits of oral contraceptives. Society for Medical Decision Making, Phoenix, AZ, October 2012.

Myers ER, Havrilesky LJ, Gierisch J, **Moorman PG**, Dinan MA, Coeytaux R, Urrutia RP, Lowery WJ, Hasselblad V, McBroom AJ, Sanders GD. Net effects of current patterns of oral contraceptive use on potentially fatal outcomes in the United States. Society for Medical Decision Making, Phoenix, AZ, October 2012.

Stouder A, Melcher B, Morgan PA, **Moorman PG**, Lin L, Stem J. Satisfaction Guaranteed? An Analysis of Lecturer Characteristics Associated with Physician Assistant Student Satisfaction. Physician Assistant Education Association Annual Education Forum, Seattle, WA, November 2012.

Moorman PG. The African American Cancer Epidemiology Study (AACES). Ovarian Cancer in Women of African Ancestry Emerging Consortium Meeting. Bethesda, MD, April 2013.

Moorman PG. Ovarian Cancer: What You Need to Know. Duke Cancer Institute, Cancer Awareness Workshop. Durham, NC, May, August and October 2014.

Moorman PG. Ovarian Cancer in African American Women: The Challenges of Studying a Less Common

Cancer in a Minority Population. Duke Cancer Institute Cancer Control and Population Sciences Seminar Series. Durham, NC, July 2014.

CONSULTANT APPOINTMENTS

National Institutes of Health, Center for Scientific Review

- Epidemiology and Disease Control Subcommittee 2 (EDC-2): Oct. 2000, Feb. 2001
- Special Emphasis Panels: Nov. 2001, Mar. 2002, Nov. 2002, Nov. 2003, July 2004, Nov. 2004, June 2005, Mar. 2006, Nov. 2006, Mar. 2007, July 2007, Nov. 2008, June 2009, July 2009, July 2010, Oct. 2010, Sept. 2011, Dec. 2013, Mar. 2017, Nov. 2017
- Small Grants Program for Cancer Epidemiology: Nov. 2001, Mar. 2003, June 2016, Mar. 2017, June 2017, June 2018, Nov. 2018
- National Cancer Institute, Program Project Review: Jan. 2003, Aug. 2003, Dec. 2003.
- SPORE (Specialized Program of Research Excellence) Review: Breast Cancer Feb. 2005, Ovarian Cancer June 2008, Feb. 2009.

Centers for Disease Control and Prevention. Defining the Public Health Research Agenda for Ovarian Cancer. Invited panel participant. Nov. 2008.

Susan G. Komen for the Cure, Study Section Chair for Post-Doctoral Fellowship in Risk and Prevention, 2010.

Susan G. Komen Breast Cancer Foundation, Study Section Chair for Risk, Prevention and Epidemiology, Member of Programmatic Review Committee, 2005 – 2007.

Susan G. Komen for the Cure/Susan G. Komen Breast Cancer Foundation, Scientific Reviewer, 2003 - 2011.

Department of Defense Breast Cancer Research Program Scientific Peer Review, 1998, 2005, 2007, 2008, 2009, 2013.

Department of Defense Breast Cancer Research Program, Study Section Chair for Training - Epidemiology and Prevention, 2013.

Department of Defense Ovarian Cancer Research Program Scientific Peer Review, 2015, 2016.

Department of Defense Ovarian Cancer Research Program, Study Section Chair for Investigator Initiated Research II, 2018.

National Cancer Institute, Center for Global Health, Data Monitoring Committee for United States – Latin American Cancer Research Network, 2013

CODA, Inc., Research Triangle Park, NC. IRB member, 2004.

National Institute of Environmental Health Sciences Special Emphasis Panel, Technical Evaluation of Support Services for Epidemiology, NIEHS Epidemiology Branch. May 1998.

PROFESSIONAL AWARDS AND SPECIAL RECOGNITIONS

Honorary Physician Assistant, Duke University Medical Center Physician Assistant Program - 2018

Certificate of Appreciation, Duke University Medical Center Physician Assistant Program – 2008

Delta Omega, Public Health Honorary – 1994

The Endocrinologist, Editorial Prize for Volume II – 1993

Research Service Award, National Cancer Institute - 1988-91

Edward E. Smismann Award for Medicinal Chemistry, University of Kansas – 1980

Walter F. Enz Award for Pharmaceutical Chemistry, University of Kansas – 1980

Watkins-Berger Scholarship, University of Kansas - 1975-1980

State of Kansas Scholarship, University of Kansas - 1976-1980

ORGANIZATIONS AND PARTICIPATION

University of North Carolina School of Public Health Alumni Association, Epidemiology Section President, 2001-2002.

Society for Epidemiologic Research

American Pharmaceutical Association

TEACHING RESPONSIBILITIES

Courses Taught

Evidence Based Medicine-I, Duke University, Department of Community and Family Medicine, Physician Assistant program. Primary instructor, 2004-2017.

Evidence Based Medicine-II, Duke University, Department of Community and Family Medicine, Physician Assistant program. Co-Instructor, 2003-2018.

Evidence Based Medicine-I, Duke University, Department of Community and Family Medicine, Physician Assistant program. Lecturer and seminar instructor, 2003.

Epidemiology and Research Methods (PAP 255), Duke University, Department of Community and Family Medicine, Physician Assistant program. Seminar instructor, 2001-2002.

Epidemiology of Cancer (CDE 532B), Yale University, Department of Epidemiology and Public Health. Course director, 1997-2000.

Co-developer of departmental Master's Comprehensive Examination, University of North Carolina-Chapel Hill, Department of Epidemiology, 1995-1996.

Cancer Epidemiology (EPID 233), University of North Carolina-Chapel Hill, Department of Epidemiology, Teaching Assistant, 1992-1993.

Principles of Epidemiology (EPID 160), University of North Carolina-Chapel Hill, Department of Epidemiology, Teaching Assistant, 1990.

Student Mentoring

Helena Furberg, MSPH, University of North Carolina, 1996, Committee Member

Pamela M. Marcus, PhD, University of North Carolina, 1997, Committee Member

Stella Chang, MPH, Yale University, 1997, Committee Member
Mary Riciutti, MPH, Yale University, 1999, Committee Chair
Edward A. Lew, MPH, Yale University, 1999, Committee Member
Shelley Goodstine, MPH, Yale University, 1999, Committee Member
Rupal Desai, MPH, Yale University, 1999, Committee Member
Pei-Yu Lin, MPH, Yale University, 2000, Committee Chair
Lisa Calvocoressi, Ph.D., Yale University, 2003, Dissertation Reader
Rebecca Cleveland, Ph.D., University of North Carolina, 2003, Committee Member
Leah Sansbury, Ph.D., University of North Carolina, 2004, Committee Member
Sumitra Shantakumar White, Ph.D., University of North Carolina, 2006, Committee Member
Katrina Trivers, Ph.D., University of North Carolina, 2006, Committee Member
Amy Dailey, Ph.D., Yale University, 2006, Dissertation Reader
Enid Rivera, M.D., Duke University, 2008, 3rd year Medical Student Preceptor
Alexis Gaines, Duke University, 2013, Master's Committee Member
Chioma Erundu, Duke University, 2013-14, 3rd year Medical Student Preceptor
Tolulope Teniola, Duke University 2016-17, 3rd year Medical Student Preceptor
Tengteng Wang, University of North Carolina, 2018, Committee Member

COMMITTEES AND SERVICE

Standing Committee on Misconduct in Research, Duke University School of Medicine, 2017-present
Senior Faculty Advisory Committee, Office for Research Mentoring, Duke University School of Medicine, 2016-present
Academy of Mentors, Office of Faculty Mentoring, Duke University School of Medicine, 2014-16
Society for Epidemiologic Research. Reviewer for Tyroler and Lilienfeld Prize Papers, 2015
Appointments, Promotions and Tenure Committee, Department of Community and Family Medicine, Duke University Medical Center. Committee Member, 2008-2018
Quality Assurance Sub-Committee for Clinical Research Units, Duke University Medical Center, Committee Chair, 2013-2014
Quality Assurance Sub-Committee for Clinical Research Units (formerly Site-based Research Units), Duke University Medical Center, Committee Member, 2011-2013
Path to Independence Faculty Mentoring Program, Duke University School of Medicine, Peer Reviewer, 2012-2018
Society for Epidemiologic Research. Abstract reviewer for annual meeting, 2011
Cancer Prevention, Detection and Control Research Program, Duke University Medical Center, Cancer Control Pilot Study application reviewer, 2010, 2011

Executive Council, Department of Community and Family Medicine, Duke University Medical Center
2009-present

Education Committee, Department of Community and Family Medicine, Duke University Medical Center,
2009-2017

Faculty Search Committee, Cancer Prevention, Detection and Control Research Program, 2010

Duke Cancer Institute, Editorial Advisory Committee Member, 2010-2011

Duke Comprehensive Cancer Center Annual Meeting, Judge for poster presentations, 2009

Director Search Committee, Cancer Prevention, Detection and Control Research Program, 2009

Partners Allied in Research (PAIR) Pilot Grant application reviewer, Cancer Prevention, Detection and
Control Research Program, 2005

Editorial Reviewer

American Journal of Epidemiology

Archives of Gynecology and Obstetrics

Breast Diseases

Cancer

Cancer Causes and Control

Cancer Research

Epidemiology

Gynecologic Oncology

International Journal of Epidemiology

Journal of Community Development

J of the Women's American Medical Assn

Lancet

Nutrition and Cancer

Public Health Nutrition

Women and Health

Annals of Epidemiology

Breast Cancer Research and Treatment

British Medical Journal-Cancer

Cancer Biomarkers

Cancer Epidemiology Biomarkers and Prevention

Clinical Breast Cancer

Ethnicity and Disease

International Journal of Cancer

JAMA

Journal of the National Cancer Institute

Journal of Women's Health

Lancet Oncology

Pharmacogenomics

Trends in Molecular Medicine

CURRENT RESEARCH

Epidemiology of breast and ovarian cancer

Ovarian function after hysterectomy

Racial differences in disease risk and outcomes

Medication use and cancer risk

Etiologic factors for uterine fibroids

EXTERNAL SUPPORT - PAST

Principal Investigator	% effort	Title of Project and Funding Source	Total Costs	Duration
Barbara Hulka	25%	High-Density Lipoprotein Cholesterol and Breast Cancer, National Cancer Institute, R03, Supported dissertation research	\$72,234	1992 – 1993

Beth Newman	100%	Carolina Breast Cancer Study, Project 2 SPORE in Breast Cancer, National Cancer Institute, P50.	\$1,275,000	1992 – 1995
Beth Newman	50%	Carolina Breast Cancer Study, Project 2 SPORE in Breast Cancer, National Cancer Institute, P50.	\$2,511,146	1995 - 1996
Patricia Moorman	50%	Medication Use and Breast Cancer in a Bi-racial Population, National Cancer Institute, R29-FIRST Award.	\$498,302	1996 – 2002
Patricia Moorman	0%	Carolina Breast Cancer Study Participant Symposium, North Carolina Division of American Cancer Society Small Grant.	\$2500	1997
Patricia Moorman	0%	Carolina Breast Cancer Study Participant Symposium, Susan G. Komen Breast Cancer Foundation Small Grant.	\$5000	1997
Joellen Schildkraut	10%	Carolina Georgia Center, Cancer Genetics Network, National Cancer Institute, U-24.	\$4,028,129	2002 – 2004
Patricia Moorman	0%	Non-steroidal Anti-Inflammatory Drugs and Breast Cancer: A Study of Gene-Environment Interactions among African-American and White Women, Minority Serving Institution Partnership Grant, Pilot Funds.	\$28,040	2003 – 2004
Celette Skinner	5%	Partnerships to Eliminate Disparities in Cancer Outcomes and Research, National Cancer Institute, National Cancer Institute.	\$517,743	2002 – 2006
Patricia Moorman	0%	Diversity Supplement to RO1 AG020162 Ovarian Failure Among Hysterectomized Women, National Institute on Aging (Note: Grant was awarded but post-doc accepted another position.)	\$169,720	2006
Andrew Berchuck	5%	Biological Basis for Chemoprevention of Ovarian Cancer, Department of Defense.	\$824,000	2002 – 2007
Stephen Freedland	5%	Weight Loss and Gain and Cancer Free Survival after Radical Prostatectomy in a Multiethnic Cohort. Prostate Cancer Foundation.	\$100,000	2007-2009
Joellen Schildkraut	10%	Genetic Modifiers of BRCA1 and BRCA2, Project 3 SPORE in Breast Cancer. National Cancer Institute.	\$1,795,862	2003 – 2009
Joellen Schildkraut	10%	Molecular Epidemiology of Ovarian Cancer. National Cancer Institute.	\$3,750,000	2003 – 2010

Patricia Moorman	40%	Ovarian Failure among Hysterectomized Women. National Institute on Aging.	\$3,781,480	2003 - 2010
Patricia Moorman (Sub-contract PI)	3%	Cancer Genetics Network. National Cancer Institute.	~\$25,000	2010 – 2012
Laura Havrilesky	15%	Oral Contraceptive Use for the Primary Prevention of Ovarian Cancer. Agency for Healthcare Research and Quality	\$486,476	2010 - 2012
Jeffrey Marks	5%	Atlantic Breast and Gynecologic Clinical Validation Center. National Cancer Institute	>\$1,500,000	2010 - 2013
Cathrine Hoyo	5%	Disparities in Cervical Cancer Precursors and Deregulation of Imprinted Genes National Cancer Institute	~\$200,000	2012 – 2013
Emanuel Trabuco (Moorman, Duke PI)	2%	Anti-Müllerian Hormone as a Marker of Ovarian Reserve in Women with and without Hysterectomy. Mayo Clinic Internal Funds	\$100,000	2012 – 2013
Evan Myers	10%	Systematic Review of Cancer Screening Literature for Updating American Cancer Society Breast Cancer Screening Guidelines American Cancer Society	~\$400,000	2013 - 2014
Joellen Schildkraut	9%	Cancer Education and Career Development Training Grant. National Cancer Institute	~\$1,400,000	2009 – 2014
Patricia Moorman (Sub-contract PI)	5%	Rare Cancer Genetics Network National Cancer Institute	~\$240,000	2010 – 2016
Joellen Schildkraut (Moorman, co-PI)	20%	Epidemiology of Ovarian Cancer in African American Women National Cancer Institute	~\$12,000,000	2010 – 2017
Gillian Sanders	10%	Management of Infertility Evidence-Based Practice Center		2015-2016
Gillian Sanders	10%	Management of Labor Dystocia Evidence-Based Practice Center		2016
Gillian Sanders	15%	Office of Women's Health – Topic Development Evidence-Based Practice Center		2016
Evan Myers	5%	Comparing Management Options for Management: Patient-centered Results for Uterine Fibroids (COMPARE-UF) PCORI	~\$19,000,000	2014 – 2018

EXTERNAL SUPPORT - CURRENT

Principal Investigator	% effort	Title of Project and Funding Source	Total Costs	Duration
Joellen Schildkraut (Moorman, sub-contract PI)	13%	Exploring Factors Related to Racial Disparities in Ovarian Cancer Incidence and Survival: The OCWAA (Ovarian Cancer in Women of African Ancestry) Consortium National Cancer Institute	~\$450,000	2017 - 2021

PERSONAL INFORMATION

Work address: DUMC Box 2715, 2424 Erwin Road, Suite 602, Durham, NC 27705

Work phone #: (919) 681-4557

E-mail address: patricia.moorman@duke.edu

Home address: 3 Skipwith Court, Durham, NC 27707

Home phone #: (919) 419-9301

Marital status: Married

Spouse's name: Allan R. Moorman, Ph.D.

Exhibit 85

Patricia G. Moorman, M.S.P.H., Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

-----X

IN RE: JOHNSON & JOHNSON

TALCUM POWDER PRODUCTS	MDL No.:
MARKETING, SALES PRACTICES,	
AND PRODUCTS LIABILITY	16-2738 (FLW)(LHG)
LITIGATION	

THIS DOCUMENT RELATES TO
ALL CASES

-----X

VIDEOTAPED DEPOSITION OF
PATRICIA G. MOORMAN, M.S.P.H., PH.D.

FRIDAY, JANUARY 25, 2019

9:04 A.M.

Taken by the Defendants
at Cambria Hotel & Suites Durham
2306 Elba Street
Durham, North Carolina 27705

- - -

Reported by Sophie Brock, RPR, RMR, RDR, CRR

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
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Patricia G. Moorman, M.S.P.H., Ph.D.

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1	INDEX OF EXHIBITS (Continued)		1	P R O C E E D I N G S
2	NUMBER	DESCRIPTION MARKED	2	THE VIDEOGRAPHER: We are now on
3	Exhibit 19	National Cancer Institute PDQ 151	3	record. Today's date is January 25th, 2019, and the
4		titled "Ovarian, Fallopian Tube,	4	time is approximately 9:04 a.m. This is the
5		and Primary Peritoneal Cancer	5	videotaped deposition of Dr. Patricia Moorman.
6	Exhibit 20	Epidemiology Article titled 165	6	Could counsel please now introduce
7		"Perineal Talc Use and Ovarian	7	themselves for the record, and then our court reporter
8		Cancer, A Systematic Review and	8	will swear in the witness.
9	Exhibit 21	Review Article titled "Genital . . . 169	9	MR. JAMES: Scott James for the Johnson
10		use of talc and risk of ovarian	10	& Johnson Defendants.
11		cancer: a meta-analysis," by	11	MS. BRENNAN: Jessica Brennan for the
12	Exhibit 22	Research Report titled "Perineal . . 173	12	Johnson & Johnson Defendants.
13		use of talc and risk of ovarian	13	MS. FOSTER: Jennifer Foster for Imerys
14	Exhibit 23	Anticancer Research Article 175	14	Talc America, Inc.
15		titled "Perineal Application of	15	MR. DONATH: Jonathan Donath for Imerys
16		Cosmetic Talc and Risk of Invasive	16	Talc, Inc.
17		Epithelial Ovarian Cancer: A	17	MS. APPEL: Renée Appel, here for
18	Exhibit 24	Meta-analysis of 11,933 Subjects	18	Personal Care Products Council.
19		from Sixteen Observational	19	MR. MIZGALA: James Mizgala for PTI.
20		Studies," by Michael Huncharek,	20	MR. FINDEIS: Alastair Findeis,
21		et al.	21	Plaintiffs' Steering Committee.
22	Exhibit 25	JNCI Article titled "Perineal . . . 202	22	MR. FARIES: Steve Faries for the
23		Powder Use and Risk of Ovarian	23	Plaintiffs.
24		Cancer," by Serena C. Houghton,	24	MS. PARFITT: Michelle Parfitt for the
25		et al.	25	Plaintiffs.

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1	INDEX OF EXHIBITS (Continued)		1	Whereupon,
2	NUMBER	DESCRIPTION MARKED	2	PATRICIA G. MOORMAN, M.S.P.H., PH.D.
3	Exhibit 26	Journal of the National Cancer . . . 205	3	having first been duly sworn/affirmed,
4		Institute Article, titled	4	was examined and testified as follows:
5		"Prospective Study of Talc Use and	5	EXAMINATION BY COUNSEL FOR THE
6	Exhibit 27	PLOS ONE Research Article titled . . 227	6	JOHNSON & JOHNSON DEFENDANTS
7		"Comparison of Estimates between	7	BY MR. JAMES:
8		Cohort and Case-Control Studies in	8	Q. Good morning, Dr. Moorman.
9		Meta-Analyses of Therapeutic	9	A. Good morning.
10	Exhibit 28	AACR Journal Research Article . . . 234	10	Q. My name is Scott James. We've had the
11		titled "Association between Body	11	pleasure of meeting before the deposition. I'm
12		Powder Use and Ovarian Cancer: The	12	counsel for the J&J Defendants in this matter.
13		African American Cancer	13	Do you understand that?
14	Exhibit 29	AACR Journal Article titled "Body . . 237	14	A. I do.
15		Powder and Ovarian Cancer Risk -	15	Q. Super. Could you state your name for the
16	Exhibit 30	International Journal of Cancer . . . 273	16	record, please.
17		Article titled "Perineal Talc	17	A. My name is Patricia Moorman.
18		Exposure and Epithelial Ovarian	18	Q. And you have been deposed before in a talc
19		Cancer Risk in the Central Valley	19	ovarian cancer case; correct?
20	Exhibit 31	Paper titled "Systematic Review . . . 307	20	A. Yes, I have.
21		and Meta-Analysis of the	21	Q. And you've testified on behalf of the
22		Association between Perineal Use of	22	Plaintiffs in that case; correct?
23		Talc and Risk of Ovarian Cancer,"	23	A. Yes, I did.
24		by Mohamed Kadry Taher, et al.	24	Q. And the allegations in that case were that
25			25	cosmetic talc powders cause ovarian cancer; correct?

3 (Pages 6 to 9)

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<p>1 A. That's correct.</p> <p>2 Q. You were deposed in the Ingham case.</p> <p>3 Do you recall the name of the case?</p> <p>4 A. Yes, I do.</p> <p>5 Q. And you were last deposed in that case in</p> <p>6 March of 2018. Do you recall that?</p> <p>7 A. Yes, I do.</p> <p>8 Q. Has there been any change in your employment</p> <p>9 status since your March 2018 deposition?</p> <p>10 A. I am still a professor at Duke University,</p> <p>11 yes.</p> <p>12 Q. Has there been any change in your work or</p> <p>13 teaching activities since your deposition?</p> <p>14 A. Yes.</p> <p>15 Q. What are those changes?</p> <p>16 A. I am in a preretirement transition, and so</p> <p>17 I have been reducing my effort. And so I do not --</p> <p>18 I'm not doing as much teaching as I was a year ago.</p> <p>19 Q. Other than that fairly significant change,</p> <p>20 are there any other changes in your teaching or work</p> <p>21 activities since the deposition?</p> <p>22 A. No.</p> <p>23 Q. Have you done any new expert witness work</p> <p>24 since the last deposition other than the talc MDL that</p> <p>25 we're here about today?</p>	<p>1 A. I'm afraid I'm a little bit unclear about the</p> <p>2 particular cases. I understand that this is an MDL</p> <p>3 case. I have been in touch with attorneys about</p> <p>4 various cases since, you know, 2016, but I'm a little</p> <p>5 bit unclear about the distinctions.</p> <p>6 Q. In preparing for today's deposition for the</p> <p>7 talc MDL, did you meet with counsel?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And who did you meet with?</p> <p>10 A. I have met with the individuals here,</p> <p>11 Michelle Parfitt, Steve Faries, Alastair, and -- I'm</p> <p>12 blanking on his last name all of a sudden -- and Jeff</p> <p>13 Gibson.</p> <p>14 Q. Are those the only attorneys that you've met</p> <p>15 with regard to your deposition today?</p> <p>16 A. Yes.</p> <p>17 Q. In preparing your MDL talc report, are there</p> <p>18 any other attorneys that you worked with other than</p> <p>19 the ones that you just mentioned with regard to the</p> <p>20 MDL?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 You may answer.</p> <p>23 I just wanted to make sure that -- I believe</p> <p>24 he's asking the names of people, not the</p> <p>25 communications.</p>
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<p>1 A. No, I have not.</p> <p>2 Q. And you understand that we are taking your</p> <p>3 deposition today in the talc MDL; correct?</p> <p>4 A. Yes.</p> <p>5 Q. Who first contacted you about serving as an</p> <p>6 expert in the talc MDL?</p> <p>7 A. It was -- let's see -- Jeff Gibson was the</p> <p>8 first person who contacted me about talc litigation.</p> <p>9 Q. When you say "talc litigation," are you</p> <p>10 referring to the Ingham case?</p> <p>11 A. I'm afraid that I'm a little unclear on --</p> <p>12 you know, there are multiple attorneys, multiple</p> <p>13 cases, and I don't know who was the Defendant and when</p> <p>14 he first approached me.</p> <p>15 Q. Understood.</p> <p>16 A. Or the Plaintiff, rather. I'm sorry.</p> <p>17 Q. Do you recall the time frame that Mr. Gibson</p> <p>18 contacted you?</p> <p>19 A. It was in summer of 2016.</p> <p>20 Q. Are you retained in any talc cases other than</p> <p>21 the talc MDL and the Ingham case?</p> <p>22 A. Not to my knowledge, no.</p> <p>23 Q. Sitting here today, do you have the ability</p> <p>24 to distinguish as to whether any attorney contacted</p> <p>25 you specifically about the talc MDL?</p>	<p>1 MR. JAMES: Yes.</p> <p>2 THE WITNESS: Okay. I believe that on</p> <p>3 teleconferences, Chris Tisi was also on one of the --</p> <p>4 at least one of the teleconferences, probably more</p> <p>5 than one.</p> <p>6 BY MR. JAMES:</p> <p>7 Q. Was Mr. Tisi involved in teleconferences</p> <p>8 pertaining to the report that you authored?</p> <p>9 A. Yes.</p> <p>10 Q. And, again, I'm not asking you about the</p> <p>11 substance of the communications, just the</p> <p>12 identification of the attorneys that you've worked</p> <p>13 with. Okay?</p> <p>14 A. Okay.</p> <p>15 Q. Are there any other attorneys that you've</p> <p>16 worked with on the MDL report?</p> <p>17 A. None that I recall.</p> <p>18 Q. Are you working with any of the counsel that</p> <p>19 you just identified on any other litigation or</p> <p>20 matters?</p> <p>21 A. No, I am not.</p> <p>22 Q. Okay. Today at the deposition, we'll follow</p> <p>23 the same ground rules as the Ingham deposition. So</p> <p>24 I know that you're familiar with them, but as a</p> <p>25 reminder, my questions will be verbal and I ask that</p>

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<p>1 your answers be verbal as well. Okay?</p> <p>2 A. Okay.</p> <p>3 Q. And that's so the court reporter can take</p> <p>4 down what you're saying and can take down what I'm</p> <p>5 saying as well.</p> <p>6 Also, Michelle has told you this, but</p> <p>7 anytime you need a break, just let us know and we'll</p> <p>8 be happy to accommodate you. Okay?</p> <p>9 A. Okay.</p> <p>10 Q. And if you have any -- if you have any -- let</p> <p>11 me rephrase that.</p> <p>12 If you don't understand any questions that</p> <p>13 I ask you, please ask me to rephrase. Okay?</p> <p>14 A. Okay.</p> <p>15 Q. Great.</p> <p>16 What are you charging Plaintiffs' counsels</p> <p>17 in the MDL?</p> <p>18 A. My rate is \$400 per hour.</p> <p>19 Q. How much have you invoiced in the MDL to</p> <p>20 date?</p> <p>21 A. For the MDL, I believe it is 21,000.</p> <p>22 Q. Okay. And prior -- sorry. Did I cut you</p> <p>23 off?</p> <p>24 A. No, you did not.</p> <p>25 Q. This morning, your counsel handed me a copy</p>	<p>1 MS. PARFITT: And I've just got to add</p> <p>2 some clarity to that.</p> <p>3 MR. JAMES: Sure.</p> <p>4 MS. PARFITT: There might be some</p> <p>5 overlap. I think that's the problem. There might</p> <p>6 just be some overlap.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Are there any invoices that you have prepared</p> <p>9 for your work in the talc litigation that you have not</p> <p>10 produced to us today in the MDL, be it Exhibit 1 or in</p> <p>11 your work in Ingham?</p> <p>12 A. These are the only invoices related to the</p> <p>13 talc litigation, period.</p> <p>14 Q. And do you have an estimate of -- when you</p> <p>15 say that these are the only invoices for the talc</p> <p>16 litigation -- and if these questions continue to be</p> <p>17 confusing, let me know -- but are there other invoices</p> <p>18 that you submitted in the Ingham case that are not</p> <p>19 part of Exhibit 1?</p> <p>20 A. No. These are all the invoices submitted.</p> <p>21 Q. We got there finally. Sorry about that.</p> <p>22 A. Okay.</p> <p>23 Q. Have you discussed your work in this</p> <p>24 litigation with any other experts who are working on</p> <p>25 behalf of the Plaintiffs?</p>
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<p>1 of the invoices that you furnished in the MDL, and I'm</p> <p>2 going to mark this as Exhibit No. 1.</p> <p>3 (Exhibit No. 1 was marked for identification.)</p> <p>4 BY MR. JAMES:</p> <p>5 Q. Exhibit No. 1 is containing four invoices.</p> <p>6 I'm going to hand those to you and ask you to confirm</p> <p>7 that those are the invoices that you have prepared for</p> <p>8 your work in the MDL.</p> <p>9 A. There are some for -- that work that was done</p> <p>10 with the Ingham case, and my understanding, that's not</p> <p>11 part of the MDL.</p> <p>12 Q. That's fair. Yes.</p> <p>13 A. Okay.</p> <p>14 Q. So are the invoices that I've handed you as</p> <p>15 part of Exhibit 1, are those the invoices related to</p> <p>16 the work that you've done on the MDL?</p> <p>17 A. I -- I'm sorry. I'm -- I'm trying to answer</p> <p>18 your question, but the ones for prior -- other than</p> <p>19 the Ashcraft & Gerel, my understanding was that these</p> <p>20 were for, like, the Ingham case and the state cases,</p> <p>21 not the MDL.</p> <p>22 Q. Okay. Let me ask it this way: Are these the</p> <p>23 invoices that you've submitted to Michelle Parfitt?</p> <p>24 A. They've been submitted to the people noted on</p> <p>25 there. So --</p>	<p>1 A. No. To my knowledge, I have not.</p> <p>2 Q. Have you had any emails or other</p> <p>3 communications with Plaintiffs' experts in the talc</p> <p>4 litigation?</p> <p>5 A. No, I have not.</p> <p>6 Q. And you recall giving your testimony in the</p> <p>7 Ingham case in March 2018; correct?</p> <p>8 A. Yes, I do.</p> <p>9 Q. After that testimony that you provided, you</p> <p>10 also had an opportunity to review that testimony;</p> <p>11 correct?</p> <p>12 A. I did.</p> <p>13 Q. And do you recall preparing a single</p> <p>14 correction to the Ingham transcript?</p> <p>15 A. Yes.</p> <p>16 Q. And so I have with me a copy of what we refer</p> <p>17 to as an errata sheet, which is the correction sheet</p> <p>18 that you signed in Ingham. I'm going to mark that as</p> <p>19 Exhibit No. 2. Okay?</p> <p>20 (Exhibit No. 2 was marked for identification.)</p> <p>21 BY MR. JAMES:</p> <p>22 Q. And the way that we're configured, there's</p> <p>23 some space between me and your counsel. So when</p> <p>24 I have exhibits, as I will throughout the day --</p> <p>25 we may have to figure out how to approach this, but I</p>

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<p>1 may hand them to you and ask that you hand them over 2 since we're all miked up. 3 Okay. And do you recognize your handwriting 4 on that Exhibit? 5 A. I do. 6 Q. Does that reflect the correction that you 7 made to your testimony? 8 A. Yes, it does. 9 Q. And if you flip over to the other side of 10 Exhibit 2, does that contain your signature? 11 A. Yes, it does. 12 Q. By signing that errata sheet, you confirmed 13 that the testimony that you gave in Ingham was true 14 and correct; correct? 15 A. Yes. 16 Q. Do you still stand behind the testimony that 17 you provided in Ingham today? 18 A. Yes, I do. 19 Q. Subject to the one correction that you made; 20 correct? 21 A. Yes, I do. 22 Q. Sitting here today, do you believe there are 23 any other changes or corrections that you need to make 24 to your testimony in Ingham? 25 A. I can't think of any, no.</p>	<p>1 A. I am. 2 Q. Okay. So for purposes of the record, this 3 morning, before the deposition, your counsel handed me 4 a copy of your updated CV. 5 Is that what you're looking at right now? 6 A. Yes, it is. 7 Q. Okay. I'm going to mark a copy of that as 8 Exhibit No. 3. 9 (Exhibit No. 3 was marked for identification.) 10 MR. JAMES: Michelle, you have a copy, 11 I presume? 12 MS. PARFITT: Actually, I think I gave 13 them all to you. Sorry. 14 MR. JAMES: Again, apologies for having 15 to handle it that way. 16 THE WITNESS: Oh, I'm sorry. 17 MS. PARFITT: Thank you. 18 THE WITNESS: Okay. The article that 19 I was referring to is -- the first author is Park. 20 The title of the article is "Benign gynecologic 21 conditions are associated with ovarian cancer risk in 22 African-American women: A case-control study." 23 And I was a coauthor on that paper, and talc 24 was included as a potential confounder. 25</p>
Page 19	Page 21
<p>1 Q. Did you review your Ingham deposition in 2 preparation for today's deposition? 3 A. I did within the last few weeks, yes. 4 Q. And so when you've reread the transcript in 5 the last few weeks, did you see anything in that 6 transcript that you wanted to correct? 7 A. No. 8 Q. Since your Ingham deposition in March of 9 2018, have you authored any publications or articles 10 pertaining to talc, asbestos, or ovarian cancer risk 11 factors? 12 A. Yes, I have. 13 Q. Okay. And let's break up that, then. 14 Have you authored any articles pertaining to 15 talc? 16 A. I have not authored any articles that 17 directly address talc as the main focus of the paper. 18 Talc has been mentioned in at least one paper as a 19 potential confounder. 20 Q. And what was the name of that article, 21 please. 22 A. If you'll give me just a moment, let me 23 look -- 24 Q. Dr. Moorman, are you looking at a copy of 25 your CV?</p>	<p>1 BY MR. JAMES: 2 Q. And, for the record, can you tell us the 3 number of the item you're looking at on your CV? 4 A. Okay. On page 14, it is Article No. 120. 5 Q. And in that paper, Dr. Moorman, did you say 6 that you described talc as a potential confounder? 7 A. Yes. 8 Q. In that paper, did you include a disclosure 9 of your involvement in this talc litigation as an 10 expert for the Plaintiffs? 11 A. I disclosed it -- actually, I had a 12 discussion with the senior author on this paper, who's 13 Michele Cote, and disclosed what I was doing. And she 14 was -- she actually said she had also done some work 15 related to talc and ovarian cancer and she was going 16 to check with the editor and see if it required a 17 disclosure. And so there was no disclosure. So 18 apparently the editor did not feel it was warranted. 19 Q. So the article, as published, does not 20 contain a disclosure of your involvement in the 21 litigation; correct? 22 A. That is correct. 23 Q. Did you review the disclosure requirements of 24 the journal in which the article was published? 25 A. I can't remember if I specifically looked at</p>

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<p>1 that journal's requirements. I don't recall if I did 2 or not.</p> <p>3 Q. Do you believe that it is important -- for an 4 author who's working on an article for a publication 5 pertaining to an issue that she's testifying about in 6 litigation, do you believe it's important to disclose 7 that to the reader of the article?</p> <p>8 A. I think that it is important to disclose it 9 in conjunction with the journal's policies, as I 10 described. I did disclose it to the corresponding 11 author, who said she was going to discuss it with the 12 editor. So I think that I did what was appropriate.</p> <p>13 Q. Did you communicate your involvement in the 14 litigation to anyone with the journal?</p> <p>15 A. I did not. It is typical that the 16 communication with the journal is through the 17 corresponding author.</p> <p>18 Q. Have you attempted to amend any disclosures 19 in your prior papers since the last deposition?</p> <p>20 MS. PARFITT: Objection. Form.</p> <p>21 THE WITNESS: I do --</p> <p>22 MR. JAMES: You're looking at your 23 counsel. Michelle can correct me if I'm wrong. She's 24 allowed to make the objections. And once she does, 25 unless she tells you not to answer, you may answer.</p>	<p>1 Q. Did they communicate with you about the 2 disclosure in a written format?</p> <p>3 A. It was an email communication.</p> <p>4 Q. Was it a single email, or was it multiple 5 emails?</p> <p>6 A. As I recall, I sent an email to the editor 7 disclosing the situation, and he -- I think he 8 responded that, yes, it should be disclosed. And then 9 I believe there was another email from -- I don't 10 know -- an editorial assistant or someone asking 11 specifically what was the -- what was the wording of 12 the disclosure that I wanted to make, and I gave them 13 that.</p> <p>14 So it was, you know, two or three emails, 15 but...</p> <p>16 Q. Do you still have that email traffic in your 17 possession?</p> <p>18 A. Probably.</p> <p>19 Q. It's on your computer?</p> <p>20 A. I would think so.</p> <p>21 Q. Okay. Could you ensure that you preserve 22 that email traffic for us, please.</p> <p>23 A. Yes.</p> <p>24 MR. JAMES: And then, Michelle, we will 25 request a copy of the email traffic.</p>
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<p>1 MS. PARFITT: That's fine.</p> <p>2 THE WITNESS: Okay. Yes. In my last 3 deposition, there was an article that I was one of 40 4 authors that looked at about 20 different risk factors 5 for ovarian cancer. I acknowledged in my deposition 6 that it was an oversight. In my career, you know, 7 spanning 25 years, I've never had to make disclosures 8 about potential conflicts of interest. I acknowledged 9 that it was an oversight on my part. When it was 10 brought to my attention, I contacted the journal, and 11 they said, "Okay. What's your disclosure?" And 12 I disclosed it.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. So just to be clear, this was after the 15 deposition; correct?</p> <p>16 A. It was.</p> <p>17 Q. Is this the Peres paper?</p> <p>18 A. Yes.</p> <p>19 Q. Did they respond to you in any way about the 20 reported conflict?</p> <p>21 A. The editor just said, "Okay. What is your 22 disclosure?"</p> <p>23 And I gave it to him. And I believe that 24 they subsequently published a correction to the 25 article.</p>	<p>1 MS. PARFITT: We'll certainly take it 2 under advisement, sure.</p> <p>3 BY MR. JAMES:</p> <p>4 Q. Do you have any similar written 5 communications about the disclosure with the paper 6 that we just discussed, the Park paper?</p> <p>7 A. No, I do not. That was a telephone 8 conference.</p> <p>9 Q. Other than the Park article that you just 10 identified, have you authored any other articles since 11 your last deposition concerning talc, asbestos, or 12 risk factors for ovarian cancer?</p> <p>13 A. As you can see on my CV, since the last 14 deposition, Article No. 121 is a paper on effect of 15 cultural, folk, and religious beliefs on delays in 16 diagnosis of ovarian cancer. I was first author on 17 that paper.</p> <p>18 Article 119, first author Anderson, was 19 looking at individual, social, and societal correlates 20 of health-related quality of life among 21 African-American survivors of ovarian cancer.</p> <p>22 And I was a coauthor on a paper by Mills 23 that was looking at immune regulatory molecular 24 expression.</p> <p>25 Q. Since your Ingham deposition, have you</p>

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<p>1 authored any articles that pertain to talc or asbestos 2 other than the Park article? 3 A. No. 4 Q. Are you currently working on any articles or 5 publications that pertain to the issues addressed in 6 your expert report? 7 A. I am a coauthor on a paper that is in 8 preparation that is describing the OCWAA Consortium, 9 which stands for Ovarian Cancer in Women of African 10 Ancestry. And this is a relatively newly formed 11 consortium, and it's describing the overall structure 12 of the consortium and some of the factors that we 13 intend to consider. And in the draft of the paper, 14 talc is included along with a long list of other risk 15 factors that we will be considering. 16 Q. Is that paper in draft form? 17 A. It is in draft form. It's being -- yeah, it 18 has not been submitted yet. 19 Q. So it has not been submitted for peer review? 20 A. No, it has not. 21 Q. Is talc mentioned in the context of a 22 potential confounder, like the Park paper? 23 MS. PARFITT: Object to form. 24 THE WITNESS: Talc is mentioned in that 25 paper as one of many ovarian cancer risk factors that</p>	<p>1 communications or written paperwork about your 2 conflict for that paper? Your litigation disclosure 3 for that paper? Is there anything in writing about 4 that to anyone or the journal itself, or a journal? 5 A. At this point, no, because it is still in 6 draft form. It's not ready to be submitted. 7 Q. Okay. Other than the papers we have 8 discussed this morning, are there any other papers 9 that you -- that are works in progress that discuss 10 talc or asbestos that you're working on? 11 A. Another paper that is in progress is looking 12 at infertility as a risk factor for ovarian cancer. 13 And talc is, again, considered as a potential 14 confounder of that association. 15 So, again, draft form. It hasn't been 16 disclosed yet because it's not at the point where one 17 would disclose that. 18 Q. Okay. And you answered my next question, and 19 that's fine. So thank you. 20 Can you identify the coauthors on the paper 21 that you've just -- that you just mentioned, the 22 infertility paper? 23 A. The infertility paper? Okay. This was work 24 that was done with a medical student, Tolu Teniola is 25 the medical student that I was working with. And then</p>
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<p>1 we hope to examine in this -- within this consortium. 2 BY MR. JAMES: 3 Q. So one of the purposes of that paper, as 4 you've described, is that you will be looking at the 5 association between talc and ovarian cancer; is that 6 correct? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: It is -- the purpose of 9 the paper is to describe the consortium. So there is 10 relatively little data about risk factors for ovarian 11 cancer among African -- African-American women, or 12 women of African ancestry. And so the purpose of the 13 paper is not focused just on talc, but it is 14 describing how the consortium hopes to compare risk 15 factors for ovarian cancer between African-American 16 and white women. So talc is among a long list of risk 17 factors that will be considered as we progress with 18 this consortium. 19 BY MR. JAMES: 20 Q. Have you yet disclosed your involvement in 21 the litigation with respect to that paper? 22 A. The -- I will disclose it when the paper will 23 be submitted, which is the typical time when such a 24 disclosure would be made. 25 Q. Have you engaged in any written</p>	<p>1 all of the AACES -- this is, again, African American 2 Cancer Epidemiology Study, which is an ovarian cancer 3 study that I've worked on for about the last nine or 4 ten years, and so all of the collaborators on that 5 study. 6 And when you look at the CV, the papers that 7 come from AACES, it's Dr. Schildkraut, Dr. Bondy, 8 Dr. Cote. It's a large multicenter study; there are 9 many coauthors, and so they would all be included. 10 Q. And with respect to the other 11 work-in-progress paper that you have identified, can 12 you identify the coauthors on that paper. 13 MS. PARFITT: Are you speaking of the 14 infertility paper? 15 MR. JAMES: The first question was 16 about the infertility. So now we're back to the first 17 work-in-progress paper that you identified. 18 THE WITNESS: Okay. So the study 19 describing the OCWAA Consortium, is that what you're 20 asking me about? 21 BY MR. JAMES: 22 Q. Yes, Doctor. Thank you for clearing that up. 23 A. Okay. So it includes -- again, this is a 24 multicenter study -- quite a few coauthors. They 25 would include Dr. Schildkraut, Lynn Rosenberg, Traci</p>

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<p>1 Bethea, Wendy Setiawan.</p> <p>2 Again, it's a large consortium with a lot of</p> <p>3 coauthors. There would be probably at least a dozen,</p> <p>4 probably more.</p> <p>5 Q. For both work-in-progress papers, are you</p> <p>6 aware of whether any of those coauthors are experts</p> <p>7 for the Plaintiffs in the talc litigation?</p> <p>8 A. I am not aware of -- if any of them are.</p> <p>9 Q. Have you -- are there any other works in</p> <p>10 progress that pertain to talc or asbestos that you're</p> <p>11 working on?</p> <p>12 A. No, I do not believe so.</p> <p>13 Q. Have you submitted the substance of your</p> <p>14 opinions in the MDL report to anyone for peer review?</p> <p>15 A. No, I have not.</p> <p>16 Q. Have you engaged in any internet postings,</p> <p>17 blogs, chatroom postings concerning your opinions in</p> <p>18 this litigation?</p> <p>19 A. No, I have not.</p> <p>20 Q. Have you given any presentations, speeches,</p> <p>21 or lectures concerning talc or asbestos or ovarian</p> <p>22 cancer risk factors since your March 2018 deposition?</p> <p>23 A. No, I have not.</p> <p>24 Q. Have you given any interviews, public</p> <p>25 statements, or other public speaking engagements</p>	<p>1 communications with your professional colleagues about</p> <p>2 your opinions?</p> <p>3 A. No, I have not.</p> <p>4 Q. And when I say "about your opinions," I mean</p> <p>5 about your opinions in this litigation.</p> <p>6 Is there any written communications, emails,</p> <p>7 or other writings expressing your opinions in this</p> <p>8 litigation to your professional colleagues?</p> <p>9 A. No, I do not believe so.</p> <p>10 Q. Have you had any discussions, since your</p> <p>11 Ingham deposition, with any healthcare professionals</p> <p>12 who treat ovarian cancer patients about your</p> <p>13 litigation opinions?</p> <p>14 A. No, I have not.</p> <p>15 Q. Have you prepared any letters to the editor</p> <p>16 about any of the publications that you cite in your</p> <p>17 MDL report?</p> <p>18 A. No, I have not.</p> <p>19 Q. Okay. I am going to hand you a copy of the</p> <p>20 deposition notice for this case. I'm going to mark</p> <p>21 that as Exhibit No. 4.</p> <p>22 (Exhibit No. 4 was marked for identification.)</p> <p>23 MR. JAMES: Michelle, do you need a</p> <p>24 copy?</p> <p>25 MS. PARFITT: I believe I might have</p>
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<p>1 concerning talc, asbestos, or ovarian cancer risk</p> <p>2 factors since your Ingham deposition?</p> <p>3 A. No, I have not.</p> <p>4 Q. Since your Ingham deposition -- and I'm</p> <p>5 structuring my questions sometimes this way in hopes</p> <p>6 of expediting. Okay?</p> <p>7 So since your Ingham deposition, have you</p> <p>8 discussed your opinions in this litigation with any of</p> <p>9 your professional colleagues?</p> <p>10 A. To some extent, yes.</p> <p>11 Q. Okay. And can you tell me who that is?</p> <p>12 A. I already mentioned Dr. Cote, Michele Cote,</p> <p>13 described the work that I was doing.</p> <p>14 I have mentioned some of the work that I'm</p> <p>15 doing to some of my colleagues within my department,</p> <p>16 Dr. Truls Ostbye for one, Dr. Kat Pollak for another.</p> <p>17 Q. And when you say that you've mentioned your</p> <p>18 litigation work with your department colleagues, what</p> <p>19 have you told them?</p> <p>20 A. I have basically described that I have been</p> <p>21 working as an expert witness in this -- in this case,</p> <p>22 and expressing my opinion, you know, that -- working</p> <p>23 for the Plaintiffs and my opinion that talc is a cause</p> <p>24 of ovarian cancer.</p> <p>25 Q. And have you engaged in any written</p>	<p>1 given you mine. If you would be so kind, I appreciate</p> <p>2 that.</p> <p>3 MR. JAMES: Dr. Moorman.</p> <p>4 THE WITNESS: Thank you.</p> <p>5 BY MR. JAMES:</p> <p>6 Q. Okay. Dr. Moorman, have you seen the</p> <p>7 deposition notice that I just handed you before?</p> <p>8 A. Yes, I have.</p> <p>9 Q. Okay. And you understand from your prior</p> <p>10 deposition, that this is a document that formally</p> <p>11 notices the time and place and why we're here; right?</p> <p>12 A. Yes.</p> <p>13 Q. And if you turn to page 3 of the notice, you</p> <p>14 see that there is a section for definitions, and then</p> <p>15 it follows with a list of document requests; correct?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And your counsel this morning has</p> <p>18 produced to me a copy of your invoices, a copy of your</p> <p>19 updated CV, an additional-materials-considered list,</p> <p>20 and has also indicated that the references to your MDL</p> <p>21 report are going to be available to us on a thumb</p> <p>22 drive.</p> <p>23 Other than those materials that I just</p> <p>24 described, are there any other materials that you've</p> <p>25 brought with you today that respond to this deposition</p>

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<p>1 notice?</p> <p>2 A. No, there are no other documents.</p> <p>3 MR. JAMES: Michelle, is there anything</p> <p>4 else that you brought with you that is responsive to</p> <p>5 the deposition notice?</p> <p>6 MS. PARFITT: You know, the only thing</p> <p>7 that might -- I believe you asked this, Mr. James --</p> <p>8 any notes that she might have taken.</p> <p>9 MR. JAMES: Yes, I was going to ask</p> <p>10 that.</p> <p>11 MS. PARFITT: So why don't we just wait</p> <p>12 for that. I do have something for that.</p> <p>13 MR. JAMES: Okay. Fair enough.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. Dr. Moorman, did you provide to your counsel</p> <p>16 any working copies of materials that you've reviewed</p> <p>17 for purposes of preparing your report or preparing for</p> <p>18 today's deposition?</p> <p>19 A. Can you tell me what you mean by "working</p> <p>20 copies"?</p> <p>21 Q. Sure. Have you made any notes on any of the</p> <p>22 materials that you reviewed for purposes of your work</p> <p>23 on the MDL?</p> <p>24 A. Yes. In this notebook here, there are</p> <p>25 articles. Most of them are the epidemiologic studies.</p>	<p>1 in your possession that are not contained in this</p> <p>2 binder?</p> <p>3 A. No. It's there and the report. That's it.</p> <p>4 MS. PARFITT: Mr. James, if we could,</p> <p>5 do you mind, could she have that back? In the event</p> <p>6 you start to ask her questions about it, she may want</p> <p>7 hers instead, and then we'll make sure you get it.</p> <p>8 Thank you.</p> <p>9 BY MR. JAMES:</p> <p>10 Q. And before we commenced this morning, your</p> <p>11 counsel, Ms. Parfitt, handed me a copy of the</p> <p>12 objections that they have lodged -- that the</p> <p>13 Plaintiffs have lodged to the deposition.</p> <p>14 MR. JAMES: Ms. Parfitt, do you want to</p> <p>15 mention that on the record?</p> <p>16 MS. PARFITT: Yes. If we could kindly</p> <p>17 have marked as Exhibit No. -- I believe it's 6 now.</p> <p>18 This is the Plaintiffs Steering Committee's Response</p> <p>19 and Objections to the Oral and Video Deposition of</p> <p>20 Dr. Patricia Moorman.</p> <p>21 Thank you.</p> <p>22 (Exhibit No. 6 was marked for identification.)</p> <p>23 BY MR. JAMES:</p> <p>24 Q. Dr. Moorman, I'm just going to hand you a</p> <p>25 copy of this because it looks like you're keeping a</p>
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<p>1 And on some of them, I have notes that basically help</p> <p>2 me kind of categorize and -- categorize the articles</p> <p>3 and some of the main things that they looked at. You</p> <p>4 know, did they address dose-response? Did they look</p> <p>5 at histology? Those types of things. It was just to</p> <p>6 kind of help me sort them out.</p> <p>7 Q. And you brought that binder with you here</p> <p>8 today; correct?</p> <p>9 A. Correct.</p> <p>10 MR. JAMES: Michelle, I'm going to mark</p> <p>11 that as Exhibit No. 5.</p> <p>12 MS. PARFITT: You can. What I would</p> <p>13 ask, last evening we didn't have the ability to get</p> <p>14 everything copied. So what we will do is, we can mark</p> <p>15 that, and we'll make some arrangements to get that</p> <p>16 copied so we can get the originals back to</p> <p>17 Dr. Moorman.</p> <p>18 MR. JAMES: Sure. That's fine.</p> <p>19 So I'm going to mark this binder</p> <p>20 Exhibit No. 5.</p> <p>21 (Exhibit No. 5 was marked for identification.)</p> <p>22 BY MR. JAMES:</p> <p>23 Q. Dr. Moorman, other than what you've provided</p> <p>24 to me in Exhibit No. 5, are there any other notes or</p> <p>25 working copies of materials considered that you have</p>	<p>1 pile over there for us of all the exhibits. Okay?</p> <p>2 I'm not going to ask any questions about it.</p> <p>3 A. Okay.</p> <p>4 Q. Okay. Dr. Moorman, in anticipation -- or in</p> <p>5 preparation for your work on the MDL, or in</p> <p>6 conjunction with your work on the MDL, you also</p> <p>7 authored an expert report; correct?</p> <p>8 A. That is correct.</p> <p>9 Q. I'm going to mark a copy of that as</p> <p>10 Exhibit No. 7. And we'll be talking about this</p> <p>11 throughout the day today. Okay?</p> <p>12 A. Okay.</p> <p>13 (Exhibit No. 7 was marked for identification.)</p> <p>14 Q. Okay. I'm handing you Exhibit 7. Is that a</p> <p>15 copy of your report that you've authored in the MDL?</p> <p>16 A. Yes, it is.</p> <p>17 Q. Do you agree that the report defines the</p> <p>18 scope of the opinions that you intend to offer in the</p> <p>19 MDL?</p> <p>20 A. Yes.</p> <p>21 MS. PARFITT: If I may, Scott, may</p> <p>22 I just see a copy of that report?</p> <p>23 MR. JAMES: I have extra copies as</p> <p>24 well, Michelle. If you need anything, just let me</p> <p>25 know.</p>

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<p>1 MS. PARFITT: Thank you. That would be 2 great. 3 MR. FARIES: I'll be the runner on this 4 one. 5 MR. JAMES: Thank you. 6 BY MR. JAMES: 7 Q. Did you review your report prior to -- in 8 preparation -- let me start that over. 9 Did you review your report in preparation 10 for today's deposition? 11 A. Yes, I did. 12 Q. Are there any changes that you want to make 13 to the report today? 14 A. No, there are not. 15 Q. Did you write the report? 16 A. Yes, I did. 17 Q. Okay. Are all parts of the report in your 18 wording? 19 A. Yes. 20 Q. Okay. If you can turn with me, Dr. Moorman, 21 to page 41. And you see here that there is a list of 22 references; correct? 23 A. Yes. 24 Q. Okay. And if you also turn to page 50, do 25 you see that there's a separate list that begins on</p>	<p>1 transcript for Curtis Omiencinski, I do not recall 2 reviewing that at all. It might have been provided to 3 me, but I don't recall reviewing it. 4 Q. Is there any way sitting here today that we 5 can efficiently identify which items on the additional 6 materials list that you have reviewed and which you 7 haven't? 8 A. I don't know what you mean by "efficiently." 9 You know, it's kind of hard to recall exactly. You 10 know, there are lots of articles here. That might 11 have been provided to me. I don't know how I could go 12 through it in just a few minutes to say did I look at 13 it or not. It would just take some time. 14 Q. Did Plaintiffs' counsel provide you all the 15 items on this list, the additional materials list? 16 A. No, I don't believe so. I mean, some of the 17 articles I've had -- like, again, some of them just 18 kind of jump out at me, like the reference 31, 19 Fathalla, "Incessant ovulation and ovarian cancer, a 20 hypothesis," that is an article that I have probably 21 referred to dozens of times. 22 Q. So the additional materials list contains a 23 mixture of items that you had on your own and items 24 that were provided to you; is that fair? 25 A. That is correct.</p>
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<p>1 page 50, halfway down, that's titled "Additional 2 materials and data considered"? 3 A. I'm sorry -- 4 Q. On page 50. 5 A. -- let me get to the right page. 6 Yes. 7 Q. Can you explain to me the difference between 8 the reference list and the additional materials and 9 data considered list? 10 A. Okay. The reference list are the references 11 to support the opinions and the statements in the 12 report that I wrote. There are some other materials 13 that I was provided, might have read, but they just 14 did not meet the level of actually needing to be 15 referenced in the report to support a certain 16 statement. 17 Some of these I might have read in more 18 detail than others, but I feel like the reference list 19 are the ones that actually supported the statements 20 that I made in my report. 21 Q. As described by you just now, are there items 22 on the additional materials and data considered list 23 that you have not reviewed at all? 24 A. There are -- along the way, there seem to be 25 some -- like, for example, item 62, comparing a</p>	<p>1 Q. Now, do you intend to rely on any materials 2 for your opinions in this case that are not identified 3 in the reference list or the additional materials 4 list? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: I mean, I am relying on 7 the expertise that I developed over more than 25 years 8 as an epidemiologist. And so there may be 9 publications, knowledge that I have that is not 10 specifically listed here. But, in general, I think 11 that is a fairly comprehensive list. I don't know 12 that I could say that it is completely exhaustive. 13 BY MR. JAMES: 14 Q. All right. I'm going to mark now as 15 Exhibit No. 8 a copy of a list entitled "Additional 16 Materials to Dr. Patricia Moorman." 17 (Exhibit No. 8 was marked for identification.) 18 BY MR. JAMES: 19 Q. Have you seen a copy of Exhibit 8 before, 20 Dr. Moorman? 21 A. I don't think that I have seen this 22 particular list. 23 MS. PARFITT: And for the record, this 24 list was compiled by Plaintiffs' counsel, Mr. James, 25 and I'm not sure whether or not my office -- the</p>

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<p>1 materials were sent, but I'm not sure whether the list 2 was sent to Dr. Moorman. 3 MR. JAMES: Okay. 4 BY MR. JAMES: 5 Q. Looking at this list, Dr. Moorman, this list 6 was furnished to us this week. 7 Do you understand that? 8 MS. PARFITT: Objection. 9 THE WITNESS: I -- if you say so. 10 BY MR. JAMES: 11 Q. Fair enough. This list -- does this list 12 include items that you were provided after you 13 authored your MDL report? 14 A. Yes. 15 Q. This list of materials did not form the 16 opinions that you included in your MDL report; 17 correct? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: I did not have access, 20 you know, to these expert reports and all before 21 I wrote my report, no. So they did not inform my 22 report. 23 BY MR. JAMES: 24 Q. Have you reviewed the materials on this list 25 as Exhibit No. 8 in their entirety?</p>	<p>1 reports have you reviewed? 2 A. Again, I have reviewed them in different 3 levels of detail and completeness. But I have looked 4 at the report of Anne McTiernan, April 5 Zambelli-Weiner, Daniel Clarke-Pearson, David Kessler, 6 Jack Siemiatycki, Michael Crowley, Rebecca 7 Smith-Bindman, and Sonal Singh, you know, to some 8 extent. 9 And I might have looked at some of the 10 others, but those were the ones that I specifically 11 recall looking at to some extent. 12 Q. Did you ask for Plaintiffs' counsel to 13 furnish you the expert reports in the litigation? 14 A. I did not. They provided them to me without 15 asking. 16 Q. Why did you review the reports of the other 17 experts? 18 A. Intellectual curiosity is the main thing. 19 I'm always interested to learn other people's 20 perspectives. And also to see if there was any 21 additional evidence that I might consider. 22 Q. And after reviewing those reports, did you 23 find any additional evidence that you might consider 24 that you didn't list in your MDL report? 25 A. I really didn't. I thought that there was a</p>
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<p>1 A. No, not in their entirety. 2 Q. Have you reviewed some and not reviewed 3 others? Is that fair? 4 A. I have -- yes, I have reviewed some of them. 5 I have not reviewed all of them. 6 Q. Okay. Is there any way for us to, again, 7 efficiently determine today which of these you've 8 reviewed and which ones you haven't? 9 A. I -- again, I could go through them and, to 10 the best of my knowledge, tell you which ones 11 I reviewed. Again, some of them I reviewed in more 12 detail, read more completely; others I looked at 13 more -- in a more cursory way. 14 Q. Did your review of any of these additional 15 materials change the opinions that you've included in 16 your MDL report? 17 A. No, they did not change my opinion. 18 Q. Did you review all of these expert reports 19 listed? 20 A. I did not review all of them. I reviewed 21 some of them. 22 Q. Okay. And these are the Plaintiffs' expert 23 reports that are listed on this list; correct? 24 A. That is my understanding. 25 Q. Okay. Which of the Plaintiffs' expert</p>	<p>1 remarkable level of consistency in the opinions, 2 particularly among the people who were reviewing the 3 epidemiologic literature. 4 Q. Dr. Moorman, I am going to now hand you a 5 copy of the reliance materials -- which is the title 6 of the list -- that you cited in the Ingham case. 7 Okay? I'm going to mark that as Exhibit No. 9. 8 (Exhibit No. 9 was marked for identification.) 9 BY MR. JAMES: 10 Q. Does that list look familiar to you? 11 A. Yes. 12 Q. And you see on the front of that list, it 13 says it was produced on March 5th, 2018; correct? 14 A. That is correct. 15 Q. And did you prepare this list? 16 A. I did not personally prepare it, no. 17 Q. Do you know that the reliance list that you 18 produced in Ingham and the reliance list that you have 19 attached as a reference list and a materials 20 considered list to your MDL report are substantially 21 different? 22 A. I would -- 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I would not be surprised 25 to say that there are some different references cited,</p>

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<p>1 yes.</p> <p>2 BY MR. JAMES:</p> <p>3 Q. Do you understand that there's a large number</p> <p>4 of additional references that you have now cited in</p> <p>5 your MDL report?</p> <p>6 A. I -- the reference list is longer, yes.</p> <p>7 Q. Do you have any idea by how much?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: No, I do not.</p> <p>10 BY MR. JAMES:</p> <p>11 Q. Would it surprise you to find out that there</p> <p>12 are 94 new items listed in your MDL report that were</p> <p>13 not listed in your March 2018 report?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 THE WITNESS: I -- you know, as you go</p> <p>16 along, I think that it is not unusual to include more</p> <p>17 references. I didn't know the exact number of new</p> <p>18 items.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Again, did you prepare the lists that are</p> <p>21 attached to your MDL report?</p> <p>22 A. The -- the list of references, I prepared</p> <p>23 that. The list of additional items, I think that was</p> <p>24 a combination of some of what I had prepared and</p> <p>25 I think what counsel had provided to me.</p>	<p>1 have become part of the public domain since that time.</p> <p>2 Do you understand that?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: I understand that some of</p> <p>5 them had been published before my deposition in March</p> <p>6 2018.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Are there specific topics of the new</p> <p>9 materials that you added between your Ingham</p> <p>10 deposition and your MDL report?</p> <p>11 A. I'm trying to think what they might be. I --</p> <p>12 some -- I think that some of the work, for example, by</p> <p>13 Fletcher and Saed describing some of their work</p> <p>14 related to possible biological mechanisms by which</p> <p>15 talc exposure could lead to ovarian cancer -- I think</p> <p>16 that was some work that I, perhaps, had not been aware</p> <p>17 of previously. And so that's one thought that comes</p> <p>18 to mind.</p> <p>19 Q. All of the items that you added from March</p> <p>20 2018 Ingham list to your MDL list, were all of those</p> <p>21 items provided to you by Plaintiffs' counsel?</p> <p>22 MS. PARFITT: Objection. Asked and</p> <p>23 answered.</p> <p>24 THE WITNESS: I don't -- I don't think</p> <p>25 so.</p>
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<p>1 Q. When you provided your opinion in March of</p> <p>2 2018 in the Ingham case, did you do so based on a</p> <p>3 comprehensive review of the literature?</p> <p>4 A. I think that -- yes, I believe that it was a</p> <p>5 comprehensive review, particularly of the</p> <p>6 epidemiologic data.</p> <p>7 Q. Why did you expand your list of references</p> <p>8 and materials considered for the MDL?</p> <p>9 A. I think just as you acquire, you know, become</p> <p>10 aware of more references, maybe if there were any new</p> <p>11 publications, or just as I expanded the knowledge,</p> <p>12 I think that it would be appropriate to include more</p> <p>13 references.</p> <p>14 Q. Do you know that a number -- a large number</p> <p>15 of the new references and materials considered were</p> <p>16 available in the public domain or in the -- in this</p> <p>17 litigation at the time that you gave your March 2018</p> <p>18 deposition?</p> <p>19 MS. PARFITT: Objection. Form.</p> <p>20 THE WITNESS: It would not surprise me</p> <p>21 to say that -- to see that some of them were there.</p> <p>22 BY MR. JAMES:</p> <p>23 Q. So, to be clear, the additional materials</p> <p>24 that you have added between March 2018 and your MDL</p> <p>25 report, those materials are not simply materials that</p>	<p>1 BY MR. JAMES:</p> <p>2 Q. Would you say the majority of the items that</p> <p>3 you've added from March 2018 to your MDL report were</p> <p>4 provided to you by Plaintiffs' counsel?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: I don't know what</p> <p>7 quantity, what fraction was provided by counsel and</p> <p>8 which I identified.</p> <p>9 MR. JAMES: Okay. I'm going to mark as</p> <p>10 Exhibit No. 10 a copy of your references and materials</p> <p>11 considered list for the MDL report.</p> <p>12 (Exhibit No. 10 was marked for identification.)</p> <p>13 BY MR. JAMES:</p> <p>14 Q. Okay. Dr. Moorman --</p> <p>15 MS. PARFITT: Just one correction,</p> <p>16 Mr. James. I think Exhibit 10 is just identified as</p> <p>17 "references." I believe you characterized it as</p> <p>18 "references and material considered."</p> <p>19 MR. JAMES: Yeah. I think if you keep</p> <p>20 flipping, Michelle -- or Ms. Parfitt -- it contains</p> <p>21 both.</p> <p>22 MS. PARFITT: Fair enough.</p> <p>23 BY MR. JAMES:</p> <p>24 Q. Okay. And you see, Dr. Moorman, if you've</p> <p>25 had a chance to flip through it while counsel have</p>

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<p>1 been talking, you see that this Exhibit 10 includes 2 some highlighting; right? 3 A. Yes. 4 Q. The highlighting, I'll state for the record, 5 represents our effort to capture the items that have 6 been added between Ingham and your MDL report. 7 Do you see that highlighting? 8 A. Mm-hmm. 9 Q. Again, I think we discussed this earlier, but 10 does it surprise you to find out that there are 94 new 11 items on the two MDL lists? 12 MS. PARFITT: Objection. Asked and 13 answered. 14 THE WITNESS: Again, I believe that 15 I answered that question previously. 16 BY MR. JAMES: 17 Q. 13 of the 20 references that are new were 18 available to you as of March 2018. Did you know that? 19 MS. PARFITT: Objection. Asked and 20 answered. 21 THE WITNESS: Again, I answered the 22 question when you asked it previously. 23 BY MR. JAMES: 24 Q. I don't think that we've talked specifically 25 about the references, but the references -- the</p>	<p>1 "search terms" or the primary search that was done, it 2 was very simple. It was "talc" or "talcum powder" and 3 "ovarian cancer." But many times, the initial search 4 will not generate all of the articles that you would 5 need to describe the science. There may be additional 6 articles, either things that I was aware of or 7 different searches that might be done. 8 But the overall search term to find the 9 literature on talc and ovarian cancer, I did not 10 change that. 11 Would it be a good time to take a break? 12 We've been going for over an hour. 13 MR. JAMES: For sure. 14 MS. PARFITT: Certainly. 15 THE VIDEOGRAPHER: Going off record at 16 10:05 a.m. 17 (Recess taken from 10:05 a.m. to 10:18 a.m.) 18 THE VIDEOGRAPHER: Back on record at 19 10:18 a.m. 20 BY MR. JAMES: 21 Q. Dr. Moorman, are you ready to proceed? 22 A. I am. 23 Q. Great. Dr. Moorman, do you consider yourself 24 to be an expert in animal studies and talc? 25 A. No, I do not.</p>
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<p>1 references that you've cited to your MDL report, those 2 are materials that you say form the opinions issued in 3 your MDL report; correct? 4 A. Yes. 5 Q. And you added 20 new references from your 6 Ingham list to your MDL report. Do you know that? 7 A. I know that there are new references, yes. 8 Q. And did you know that 13 of the 20 new 9 references -- again, the references are the list of 10 materials that formed your MDL report -- those were 11 available before March 2018? Did you know that? 12 A. I am aware that some of them were available. 13 Would like to make the point that many of 14 the points that I make in my report can be supported 15 by many, many references. And so the fact that 16 I added new references, that's really not too 17 surprising. It's -- again, if I felt like wanted to 18 emphasize a point more strongly, including additional 19 references, I don't think that would be surprising to 20 add additional references. 21 Q. Did you change your standards or search terms 22 that you used in the Ingham literature review for the 23 MDL review? 24 MS. PARFITT: Objection to form. 25 THE WITNESS: When we talk about</p>	<p>1 Q. Do you consider yourself to be an expert in 2 cell studies and talc? 3 A. No, I do not. 4 Q. Okay. Do you consider yourself to be an 5 expert in cytotoxicity studies and talc? 6 A. No, I do not. 7 Q. Do you consider yourself to be an expert in 8 mutagenicity studies and talc? 9 A. No, I do not. 10 Q. Do you consider yourself to be an expert in 11 genotoxicity studies and talc? 12 A. No, I do not. 13 Q. Do you consider yourself to be an expert in 14 mineral testing methods? 15 A. No, I do not. 16 Q. Okay. Do you consider yourself an expert in 17 mineral characterization? 18 A. No, I do not. 19 Q. Do you consider yourself to be an expert in 20 cancer biology? 21 A. I am not a cancer biologist; however, I 22 consider cancer biology frequently in my work. 23 Q. Do you consider yourself to be an expert in 24 geology? 25 A. No, I do not.</p>

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<p>1 Q. And do you consider yourself to be an expert 2 in mining? 3 A. No, I do not. 4 Q. Do you have expertise in pathology? 5 A. I -- once again, I am not a pathologist. 6 Sometimes rely on pathology and have collaborated with 7 pathologists, but I am not an expert pathologist. 8 Q. And would you agree do that not have 9 expertise in pathology? 10 MS. PARFITT: Objection. Asked and 11 answered. 12 THE WITNESS: You asked that I -- I do 13 not have expertise in pathology. I stated that I am 14 not a pathologist, but I do know some pathology from 15 my work in ovarian cancer and other cancers over the 16 years. So to say that I have no expertise isn't -- 17 I don't think that is correct. But we both -- I 18 acknowledge that I am not a trained pathologist. 19 BY MR. JAMES: 20 Q. Do you recall being asked in Ingham if you 21 considered yourself to have expertise in pathology? 22 A. I don't recall that question, specifically. 23 Q. I'm going to hand you a copy of the 24 transcript from Ingham that I brought with me, and I'm 25 going to refer you --</p>	<p>1 BY MR. JAMES: 2 Q. Have you done anything between your March 3 deposition and today in regards to obtaining expertise 4 in pathology? 5 A. No, I have not. 6 Q. Dr. Moorman, that's all I have on the 7 transcript for right now. 8 Dr. Moorman, do you agree that, prior to 9 offering expert opinion on a particular topic, an 10 expert should be conducted to -- expected to conduct a 11 comprehensive review of the medical and scientific 12 literature on that topic? 13 A. I'm sorry, I'm reading the question. 14 I -- I think that it is important to be 15 comprehensive. I think it's also important to 16 recognize that there are expertise in different areas. 17 And so we recognize that my expertise is in 18 epidemiology, and I have supplemented that with 19 other -- information from other areas as well. 20 Q. And with respect to the epidemiology on talc 21 and ovarian cancer, do you believe you conducted a 22 comprehensive review of that body of literature? 23 A. I believe that I have. 24 Q. Do you believe you conducted a comprehensive 25 review of the literature and scientific evidence on</p>
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<p>1 MR. JAMES: And, Ms. Parfitt, I have 2 two copies, unfortunately, not three. And this will 3 be just a couple questions, Ms. Parfitt. So if you 4 bear with me -- 5 MS. PARFITT: You can just direct me to 6 the page. 7 MR. JAMES: Sure. Looking at page 280. 8 MS. PARFITT: Just bear with us both -- 9 me. All right. 10 MR. JAMES: I'm looking at lines 12 11 through 14. 12 MS. PARFITT: Thank you. 13 BY MR. JAMES: 14 Q. Do you see the question, Dr. Moorman, where 15 you were asked if you have expertise in pathology? 16 Do you see that question? 17 A. I do. 18 Q. Okay. And you answered that you do not; 19 correct? 20 MS. PARFITT: Objection. 21 THE WITNESS: Yes, that is how 22 I answered. I think that the more qualified answer 23 that I gave today is probably a more accurate 24 representation. 25</p>	<p>1 mechanism? 2 A. I considered the scientific mechanisms and, 3 again, recognizing what my expertise is. As I have 4 indicated earlier, I am not a cancer biologist. I'm 5 not a laboratory scientist. I consider some of that 6 data, but I recognize that I am not -- you know, that 7 is not my major area of expertise. 8 Q. And I do understand from your MDL report that 9 you considered biology; correct? 10 A. I did consider biology. 11 Q. And so my precise question is whether you 12 conducted a comprehensive review on the issue of 13 mechanism. 14 MS. PARFITT: Objection. Asked and 15 answered. 16 THE WITNESS: I considered it, and, 17 again, I think that there is information out there 18 that a cancer biologist would have the expertise to 19 review it in more detail because of their training, 20 which is different than the training and expertise 21 that I have. 22 MR. JAMES: I object to the 23 nonresponsive portion of the answer. 24 BY MR. JAMES: 25 Q. Dr. Moorman, did you conduct a comprehensive</p>

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<p>1 review of all of the literature on animal studies and 2 talc? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I don't believe that -- I 5 cannot say that I considered -- identified or 6 considered every animal study. 7 MR. JAMES: Object to the nonresponsive 8 answer. 9 BY MR. JAMES: 10 Q. Did you conduct a comprehensive review of the 11 literature on animal studies and talc? 12 MS. PARFITT: Asked and answered. 13 Objection. 14 THE WITNESS: I -- I believe that 15 I answered your question. I said that I don't think 16 that I identified or considered every animal study 17 related to talc and ovarian cancer. 18 BY MR. JAMES: 19 Q. Did you conduct a comprehensive review of 20 cell studies and talc? 21 A. Once again, I considered some of that 22 literature. Whether it was comprehensive or not, I -- 23 I don't think that I have the expertise to say that 24 I considered all of the cell studies and talc. 25 Q. Did you conduct a comprehensive review on the</p>	<p>1 have referred to another article. 2 Q. Did you conduct a comprehensive review of the 3 genotoxicity studies that are relevant to talc and 4 ovarian cancer? 5 A. My answer to this question is similar to the 6 answers that I have given there. 7 I have read some of the mechanistic studies. 8 I would not say that I necessarily identified every 9 relevant genotoxicity study. 10 Q. And I'm not asking you, Dr. Moorman, if you 11 did find 100 percent of the studies. I'm asking you 12 if part of your review in this case began with the 13 intention to capture that body of literature. 14 MS. PARFITT: Objection. Asked and 15 answered several times. 16 THE WITNESS: My intent was, as an 17 epidemiologist, was to be very comprehensive in my 18 area of expertise. There were certainly some other 19 related areas where I reviewed the literature, but 20 there are experts that will speak to that more 21 directly because of their expertise. 22 BY MR. JAMES: 23 Q. Okay. So will you agree with me today that 24 you have not conducted a comprehensive review of the 25 cell studies and talc?</p>
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<p>1 issue of migration in this case? 2 A. I believe -- again, I considered every study 3 that I was aware of on migration of talc. It's a 4 little bit outside my area of expertise, so I am not 5 sure that I identified every single study in that 6 regard. 7 Q. And with the methods that you applied in this 8 case, was it your intention to capture every study 9 pertaining to the issue of migration? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: I tried -- you know, my 12 intent was to read the articles that I was aware of, 13 that were brought to my attention. Because it is a 14 little bit outside my area of expertise, I cannot say 15 with 100 percent certainty that I identified every 16 single study related to migration. 17 BY MR. JAMES: 18 Q. But you testified that your intent was to 19 read the articles that you are aware of or that were 20 brought to your attention. 21 When you say brought to your attention, was 22 that by Plaintiffs' counsel? 23 A. It's some -- some of them could have been 24 brought to my attention in that way. Some of them 25 could have been -- like, an article that I read might</p>	<p>1 MS. PARFITT: Objection. Misstates her 2 testimony. 3 You may answer, Dr. Moorman. 4 THE WITNESS: I -- I think that -- 5 I think that it is fair to say that I have probably 6 not reviewed every cell study and talc. 7 BY MR. JAMES: 8 Q. Okay. Dr. Moorman, I'm going to refer you 9 back to the Ingham transcript, please, that's in front 10 of you. 11 MS. PARFITT: Are we marking this, 12 Scott? 13 MR. JAMES: We can. Sure. 14 Dr. Moorman, when we finish this, I'll take 15 that back from you and mark it as Exhibit No. 11. 16 Okay? 17 (Exhibit No. 11 was marked for identification.) 18 BY MR. JAMES: 19 Q. Dr. Moorman, if you look at page 35 of your 20 transcript, please. And if you look at lines -- it's 21 lines 11 through 17. It's a question and answer. If 22 you could review that for me. 23 A. Okay. 24 Q. And do you see that on line 16, you answered 25 in Ingham:</p>

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<p>1 "I have not done a comprehensive 2 review of those studies." 3 And there, you're referring to cell studies; 4 correct? 5 A. Yes, that is what it says here. 6 Q. Is that a truthful answer? 7 A. I think -- 8 MS. PARFITT: Objection. Form. 9 Go ahead. 10 THE WITNESS: I think that we -- you 11 know, as you have asked me the questions and I have 12 responded to them, that it's -- I have looked at some 13 of these studies. I would not have looked at all of 14 them. 15 BY MR. JAMES: 16 Q. As an epidemiologist, do you understand the 17 significance of the term "comprehensive review"? 18 A. Yes, I understand the term. 19 Q. Okay. And you understand that you have 20 testified that you conducted a comprehensive review of 21 the epidemiology literature for talc and ovarian 22 cancer; correct? 23 MS. PARFITT: Asked and answered. 24 THE WITNESS: Yes. 25</p>	<p>1 literature in greater detail. 2 Q. Have you undertaken a comprehensive review of 3 literature pertaining to the allegation that asbestos 4 may contaminate talcum powder products? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: A comprehensive review of 7 the literature pertaining to the allegation that 8 asbestos may contaminate talcum powder? 9 I have read quite a few articles and 10 documents addressing that. Whether or not I have read 11 every document addressing that, I'm not absolutely 12 sure. 13 BY MR. JAMES: 14 Q. Okay. Dr. Moorman, you're answering a 15 question that I didn't ask. And so I object to the 16 nonresponsiveness again. 17 Did you conduct a comprehensive review of 18 the body of literature assessing whether asbestos 19 contaminates talcum powder products? 20 A. I believe that I have answered your question. 21 It's -- 22 Q. Could you please answer it again. 23 A. I have read many articles on it. I do not 24 know that I have read every article related to that 25 topic, again. So...</p>
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<p>1 BY MR. JAMES: 2 Q. And so I'm asking if you have applied the 3 same comprehensive review to these other areas, 4 including cell studies, animal studies, and mechanism 5 studies. 6 MS. PARFITT: Objection. Form. Asked 7 and answered. 8 BY MR. JAMES: 9 Q. Have you conducted the same comprehensive 10 review on that body of literature that you've 11 conducted on the epidemiology? 12 MS. PARFITT: Objection. 13 THE WITNESS: Once again, I have 14 answered the question. This is not my primary area of 15 expertise. And so I have not done the review to the 16 depth and the -- as comprehensive as I have done in my 17 area of expertise, which is epidemiology. 18 BY MR. JAMES: 19 Q. Have you done a comprehensive review of the 20 epidemiology on the relationship between asbestos and 21 ovarian cancer? 22 A. I believe that I have looked at a pretty 23 comprehensive -- I've had a pretty comprehensive look 24 at the asbestos and ovarian cancer. I believe that 25 I have looked at the talcum -- talc and ovarian cancer</p>	<p>1 Q. You understand that if you were going to 2 publish an opinion in peer-reviewed literature about 3 the allegation that asbestos contaminates talcum 4 powder products, you would be expected to conduct a 5 comprehensive review of that literature; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: If I were to publish an 8 opinion in a peer-reviewed literature, you would want 9 to have a comprehensive review of the literature, yes. 10 BY MR. JAMES: 11 Q. And have you conducted a comprehensive review 12 of the literature on that topic, such that you would 13 feel comfortable providing an opinion for a 14 peer-reviewed journal? 15 MS. PARFITT: Objection. Form. 16 BY MR. JAMES: 17 Q. And the topic being the allegation that 18 asbestos contaminates talcum powder products. 19 MS. PARFITT: Objection. Form. 20 THE WITNESS: I think that I'm maybe 21 having some difficulty answering this question because 22 it would seem like this would be a topic that would be 23 more appropriately addressed by a mineralogist. And 24 I -- I actually cannot see myself writing a 25 peer-reviewed article about this because it seems</p>

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<p>1 somewhat -- it's related to the epidemiology of talc 2 and ovarian cancer, but I would not be writing an 3 article focused solely on that. 4 BY MR. JAMES: 5 Q. You understand that, in your expert report, 6 you have opined with -- that there's "credible 7 evidence" there has been asbestos in talcum power 8 products. 9 Do you recall making that conclusion in your 10 report? 11 A. Yes. 12 Q. So to support that conclusion that you 13 believe there's "credible evidence" in talcum powder 14 products, did you conduct a systematic review of the 15 literature to support that conclusion? 16 A. I did not -- 17 MS. PARFITT: I'm going to object to 18 the form of the question. Some words were left out. 19 You may answer. 20 THE WITNESS: In my report, I cited 21 literature that did support that opinion. 22 Did I conduct a systematic review that 23 identified possibly every piece of literature that 24 addressed the topic? No, I did not do that. 25</p>	<p>1 A. It was part of the basis for my opinion, 2 along with some peer-reviewed literature. 3 Q. Okay. With respect to the company documents, 4 were those documents hand-selected for you by 5 Plaintiffs' counsel? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: They were provided to me 8 by Plaintiffs' counsel. 9 BY MR. JAMES: 10 Q. Okay. When you saw those documents, did you 11 ask if there were additional documents that would 12 address the issue of asbestos contamination? 13 A. I don't know that I asked if there were 14 additional documents. It was my impression that there 15 were probably many other documents related to this 16 that were not provided to me. 17 Q. And as a scientist, wouldn't you be 18 interested in knowing if there are other documents 19 that have been produced in this litigation that rebut 20 the claim that asbestos contaminates talcum powder 21 products? 22 MS. PARFITT: Objection. Form. 23 THE WITNESS: This is an interesting 24 question because the claim had been made that 25 asbestos -- or, rather, that talcum -- talcum powder</p>
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<p>1 BY MR. JAMES: 2 Q. Do you believe that the standards for 3 providing opinions in litigation reports differ from 4 the standards for providing opinions in published 5 literature? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: No. No. I think that 8 one is trying to provide evidence to support one's 9 opinions. 10 BY MR. JAMES: 11 Q. With respect to the issue of asbestos 12 contamination, Dr. Moorman, you said you did review 13 some articles. 14 How did you characterize that? 15 A. I said that I reviewed some -- some articles 16 and some -- some documents. I don't think that 17 I reviewed every article or document that is available 18 on that topic. 19 Q. With respect to documents, are you referring 20 to company documents provided to you by Plaintiffs' 21 counsel? 22 A. That -- that's part of what I reviewed, some 23 of those documents provided by counsel. 24 Q. And looking at those documents provided the 25 basis for your opinion; is that right?</p>	<p>1 products had been asbestos-free since 1976. And it 2 is -- the documents provided, including the 3 peer-reviewed as well as the other, saying that -- 4 provide evidence that that is not an accurate 5 statement. 6 We're not saying that every container of 7 talcum powder contains asbestos, but what I was saying 8 in my report is that there is evidence that some 9 talcum powder products have asbestos in them. 10 MR. DONATH: Move to strike, 11 nonresponsive. 12 BY MR. JAMES: 13 Q. So are you changing your report -- because in 14 the report, you say that there is "credible evidence." 15 Do you recall making that conclusion? 16 A. Yes. 17 Q. As a scientist, you understand that to give 18 something credit, you would necessarily need to 19 consider both sides of the story; correct? 20 MS. PARFITT: Objection. Misstates her 21 testimony. She's... 22 You can answer, Dr. Moorman. 23 THE WITNESS: I'm sorry? 24 MS. PARFITT: I said it misstates what 25 you're trying to suggest to the ladies and gentlemen</p>

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<p>1 of the jury.</p> <p>2 But if you can answer that question again,</p> <p>3 please try and answer Mr. James' question. And</p> <p>4 look -- if you need to look at the question, please</p> <p>5 do.</p> <p>6 THE WITNESS: I think that I did -- it</p> <p>7 says "As a scientist, you understand that to give</p> <p>8 something credit, you would necessarily need to</p> <p>9 consider both sides of the story."</p> <p>10 And I think that I did consider both sides</p> <p>11 of the story.</p> <p>12 I think that, as I stated, the evidence does</p> <p>13 not suggest that every container of talcum powder has</p> <p>14 detectable asbestos in it. But my statement that</p> <p>15 there is credible evidence that some talcum powder</p> <p>16 products contain asbestos, I think that that statement</p> <p>17 is absolutely true. There is some evidence to</p> <p>18 indicate that some talcum powder -- or asbestos has</p> <p>19 been identified in some talcum powder products.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. Do you understand what Johnson & Johnson's</p> <p>22 position is with respect to that claim?</p> <p>23 A. I -- I don't know specifically. Perhaps you</p> <p>24 could -- could tell me.</p> <p>25 Q. You understand that Johnson & Johnson's</p>	<p>1 company documents and other materials to support your</p> <p>2 conclusions about asbestos contamination?</p> <p>3 A. I -- I wouldn't be able to quantify that.</p> <p>4 I don't know specifically.</p> <p>5 Q. Can you give us an estimate?</p> <p>6 A. I think it would be pretty difficult to come</p> <p>7 up with an estimate. You know, I read some documents</p> <p>8 from the company. I read documents -- some</p> <p>9 peer-reviewed literature. I reviewed documents</p> <p>10 provided by Plaintiffs' counsel.</p> <p>11 Perhaps -- I don't know. Perhaps ten -- ten</p> <p>12 hours or so.</p> <p>13 Q. When you said that you reviewed company</p> <p>14 documents, again, those are the documents provided to</p> <p>15 you by Plaintiffs' counsel; correct?</p> <p>16 A. Yes.</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: Yes, the Plaintiff</p> <p>19 provided those documents to me.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. And you did not ask Plaintiffs' counsel to</p> <p>22 provide you additional documents once you saw the</p> <p>23 first batch of documents; correct?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: I did not ask, no.</p>
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<p>1 position is that talcum powder products have not been</p> <p>2 contaminated with asbestos? Do you know that that's</p> <p>3 Johnson & Johnson's position?</p> <p>4 A. I -- if you are telling me that now, I don't</p> <p>5 know that I have -- I -- I'm trying to think what</p> <p>6 I have read. I think that, yes, I have probably read</p> <p>7 statements from the company that describes that as</p> <p>8 their position.</p> <p>9 Q. And do you know what Johnson & Johnson bases</p> <p>10 their position on?</p> <p>11 A. Not specifically.</p> <p>12 Q. Wouldn't that be pretty important to</p> <p>13 understand before making an opinion about whether</p> <p>14 there's credible evidence of asbestos contamination?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: Again, I think that when</p> <p>17 one is trying to make a statement that there is no</p> <p>18 asbestos contained in talc products, if you are</p> <p>19 finding evidence from multiple sources that there is</p> <p>20 asbestos contained in some talc products, that</p> <p>21 supports the statement that I made in report that</p> <p>22 there is credible evidence that not all talc products</p> <p>23 are asbestos-free.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. How many hours did you spend reviewing</p>	<p>1 BY MR. JAMES:</p> <p>2 Q. You also looked at litigation reports from</p> <p>3 Plaintiffs' expert regarding asbestos contamination;</p> <p>4 correct?</p> <p>5 A. Yes, I did.</p> <p>6 Q. And you understand those experts are paid</p> <p>7 litigation experts by the Plaintiffs; correct?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: Yes, I understand that</p> <p>10 they are paid by the Plaintiffs.</p> <p>11 BY MR. JAMES:</p> <p>12 Q. One of those experts is Longo; correct?</p> <p>13 A. That is correct.</p> <p>14 MS. PARFITT: Is that Dr. Longo?</p> <p>15 MR. JAMES: Thank you, Michelle.</p> <p>16 BY MR. JAMES:</p> <p>17 Q. Dr. Longo; is that correct?</p> <p>18 A. That is correct.</p> <p>19 Q. Okay. So you reviewed Dr. Longo's reports?</p> <p>20 A. I looked at them, yes.</p> <p>21 Q. Okay. Do you understand that in this</p> <p>22 litigation, Johnson & Johnson has presented experts to</p> <p>23 rebut Dr. Longo's findings?</p> <p>24 MS. PARFITT: Objection. Just let the</p> <p>25 record reflect that the defense expert reports have</p>

19 (Pages 70 to 73)

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<p style="text-align: right;">Page 74</p> <p>1 not yet been provided in this litigation, in the MDL 2 litigation, so it would have been difficult to provide 3 that to Dr. Moorman. 4 BY MR. JAMES: 5 Q. You can still answer the question. 6 A. It would not surprise me to know that there 7 were reports provided by -- that was done for the 8 defense, but I have not seen them. 9 Q. Did you ask to see them? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: I did not ask to see -- 12 no, I did not. 13 BY MR. JAMES: 14 Q. And counsel just made a note on the record 15 about these litigation reports from the defense not 16 being made available yet in the MDL. 17 Do you understand that the defense has 18 presented experts, for example, in the Ingham case to 19 rebut Dr. Longo's findings? 20 A. I was not specifically aware of that. It 21 would not surprise me, however. 22 Q. You understand Dr. Longo's litigation reports 23 that you reviewed, those are not peer-reviewed. 24 Do you understand that? 25 MS. PARFITT: Objection. Form.</p>	<p style="text-align: right;">Page 76</p> <p>1 there's no safe level of asbestos, that any level of 2 asbestos in a talcum powder product is bad for the 3 health of the people who use it. 4 Q. Do you intend to offer any opinions about the 5 purported amount of contamination in talcum powder 6 products over the course of history? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: I am not going to offer 9 an opinion about the quantity of asbestos in talcum 10 powder products. 11 BY MR. JAMES: 12 Q. Have you, in the course of forming your 13 opinions in this case, ever reviewed the FDA testing 14 of talcum powder products for the presence of 15 asbestos? 16 A. I recall reviewing a document from FDA, yes. 17 Q. Okay. And that document is not discussed in 18 your report, is it? 19 A. No, I don't think that I specifically 20 reference that. 21 Q. Why is that? 22 A. I don't -- I don't know why I didn't 23 reference it. I read it, but... 24 MR. JAMES: I'm marking Exhibit No. 11 25 [sic], talc testing information from the FDA, that I'm</p>
<p style="text-align: right;">Page 75</p> <p>1 THE WITNESS: Yes, I know that they are 2 not peer-reviewed. 3 BY MR. JAMES: 4 Q. With regard to the literature that you've 5 referenced having reviewed pertaining to the 6 allegation that talcum powder products are 7 contaminated with asbestos, what does that literature 8 say about Johnson & Johnson products specifically? 9 A. I'm trying to recall specifically. I believe 10 that some of the articles were not specific about the 11 particular brand names that they tested. I think they 12 just described them as commercially available 13 products. But I believe that -- I want to say that 14 I recall at least one that described the products as 15 being Johnson & Johnson. 16 Q. With respect to everything that you reviewed 17 pertaining to your claim in your report of "credible 18 evidence" of contamination of talcum powder products, 19 what did everything you reviewed tell us about the 20 amount of contamination in the products? 21 Do you have any opinions about amount? 22 A. I do. My opinions are that most of the 23 analyses that detected asbestos fibers in talcum 24 powder products detected low levels, and putting that 25 in the context that asbestos has been characterized as</p>	<p style="text-align: right;">Page 77</p> <p>1 handing you, Dr. Moorman. 2 (Exhibit No. 12 was marked for identification.) 3 MR. JAMES: I provided an extra copy if 4 you want to hand one to your counsel, please. Thank 5 you much. 6 MR. FARIES: This is 12. 7 MS. PARFITT: 11 is the transcript. 8 MR. JAMES: Got it. Thank you. I'll 9 fix the sticker once we finish the question. 10 MS. PARFITT: No worries. 11 BY MR. JAMES: 12 Q. Okay. Dr. Moorman, is this the document that 13 you had seen before? 14 A. I'm not sure if this is the same one or if 15 I -- no, I -- actually, I think that I did see this. 16 Q. And if you look over on page 2 of the 17 exhibit -- it's page 2 of 8 -- do you see at the 18 bottom, it says in the section "The results of FDA's 19 survey" -- do you see where I'm reading? 20 A. Yes. 21 Q. And the FDA here says (as read): 22 "The survey found no asbestos 23 fibers or structures in any of the 24 samples of cosmetic-grade raw 25 material talc or cosmetic products</p>

20 (Pages 74 to 77)

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<p>1 containing talc." 2 Did I read that correctly? 3 A. You did. 4 MS. PARFITT: Are you going to complete 5 this paragraph, or are you going to leave it at that? 6 MR. JAMES: Michelle, you'll have an 7 opportunity to ask your questions. 8 MS. PARFITT: Well, just for 9 completeness. Certainly, if that's how you'd like to 10 handle it, that's fine. 11 MR. JAMES: Okay. That's how it works. 12 MS. PARFITT: Oh, I -- Scott, you don't 13 have to educate me on how it works. I get how you're 14 working, and we'll make it work on our side too. 15 Thank you. 16 BY MR. JAMES: 17 Q. Dr. Moorman, is that conclusion cited 18 anywhere in your report? 19 A. That -- 20 MS. PARFITT: Objection to the partial 21 conclusion. 22 Please answer. 23 THE WITNESS: Right. It's -- I did not 24 put it in there. However, I considered as I was, you 25 know, evaluating this literature, what it goes on to</p>	<p>1 proportion of the talcum powder products in the US are 2 Johnson & Johnson products. 3 Q. Do you know if the FDA test results 4 specifically pertain to Johnson & Johnson products? 5 A. I'm -- I believe that some of the products 6 tested -- I believe that some of them were Johnson & 7 Johnson products, if I'm not mistaken. But I can't 8 say that with certainty. 9 Actually, when I look at the report, I do 10 see that they list Johnson's baby powder. 11 Q. And, Dr. Moorman, you're referring to page 7; 12 correct? 13 A. Yes. 14 Q. Okay. Do you understand that the FDA also 15 tested samples provided to them by the supplier of 16 talc for Johnson & Johnson products? Did you know 17 that? 18 A. I -- I think that I knew that. I believe 19 I did know that. 20 Q. Again, that's not quoted anywhere in your 21 report either, is it? 22 A. No, that is -- 23 MS. PARFITT: Object to form. 24 THE WITNESS: -- not. 25</p>
Page 79	Page 81
<p>1 say (as read): 2 "The results were limited by the 3 fact that only four talc suppliers 4 submitted samples and by the 5 number of products tested." 6 BY MR. JAMES: 7 Q. Okay. 8 A. And so it goes on to say, you know, 9 (as read): 10 "They do not prove that most or 11 all talc or talc-containing 12 cosmetic products currently 13 marketed in the US are likely to 14 be free of asbestos 15 contamination." 16 So... 17 Q. You're offering opinions in the MDL -- let me 18 re-ask this. 19 Are you offering opinions in the MDL that 20 Johnson & Johnson talcum powder products have been 21 contaminated with asbestos at some point in time? 22 A. In my opinion, I am referring to talcum 23 powder products. Okay? I don't believe in my report, 24 I ever specifically say Johnson & Johnson talcum 25 powder products, but I do recognize that a large</p>	<p>1 BY MR. JAMES: 2 Q. Before offering opinions about "credible 3 evidence," don't you think it would be important to 4 mention the findings of the FDA on such an important 5 issue? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: As I have stated before, 8 my opinion was that there is credible evidence that -- 9 from peer-reviewed articles, from some other sources 10 as well, that asbestos has been found in talcum powder 11 products. I believe that that evidence is credible. 12 I did not make the statement that it is in 13 all products, but I think that my statement that there 14 is credible evidence that some talcum powder products 15 contain asbestos I think is accurate. 16 BY MR. JAMES: 17 Q. And is that a conclusion that you would feel 18 comfortable providing in published peer-reviewed 19 literature? 20 MS. PARFITT: Objection. Form. 21 THE WITNESS: To say that there is 22 credible evidence that some talcum powder products 23 contain asbestos, I think that that -- I would feel 24 comfortable saying that based on peer-reviewed 25 literature that has found that.</p>

21 (Pages 78 to 81)

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<p>1 BY MR. JAMES: 2 Q. But you never undertook an effort to conduct 3 a comprehensive review of the literature on the topic, 4 did you? 5 MS. PARFITT: Objection. Form. Asked 6 and answered several times. 7 THE WITNESS: Yes, I feel like I -- you 8 have asked that, and I think that I have answered it. 9 BY MR. JAMES: 10 Q. What's your answer? 11 A. My answer is that I have found evidence 12 that -- from peer-reviewed literature, from other 13 documents, that some asbestos has been detected in 14 some talcum powder products. 15 Q. With regard to the company documents that you 16 reviewed that were provided to you by Plaintiffs' 17 counsel, do you consider yourself an expert in 18 reviewing the information conveyed by those documents? 19 MS. PARFITT: Objection. Form. 20 THE WITNESS: As I have indicated 21 previously, I am not a mineralogist or a geologist, 22 and so I would not consider myself an expert in 23 reviewing those types of documents. 24 BY MR. JAMES: 25 Q. Do you have any knowledge about the</p>	<p>1 BY MR. JAMES: 2 Q. Dr. Moorman, have you seen a 2014 letter from 3 the FDA addressing a request for a warning on talcum 4 powder products? 5 A. Yes, I have. 6 Q. Do you know that within that letter, the FDA 7 comments on the issue of alleged asbestos 8 contamination? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: If I could see the 11 document. It has been a while since I have actually 12 looked at it. 13 BY MR. JAMES: 14 Q. Absolutely. 15 MR. JAMES: And if counsel could remind 16 me, are we now on 13? 17 MS. PARFITT: We are indeed. 18 MR. JAMES: Thank you. 19 MS. PARFITT: You are very welcome. 20 (Exhibit No. 13 was marked for identification.) 21 BY MR. JAMES: 22 Q. Okay. Dr. Moorman, I'm handing you a copy of 23 the 2014 FDA letter with an extra copy to pass to your 24 counsel. 25 MS. PARFITT: Thank you.</p>
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<p>1 specifications that are used by Johnson & Johnson in 2 manufacturing its talcum powder products? 3 A. No, I do not. 4 Q. Do you have any expertise in the sufficiency 5 of the specifications to detect the presence of 6 asbestos? 7 A. No, I do not. 8 Q. Did you know that Johnson & Johnson produces 9 its talcum powder products in accordance with 10 specifications set out by the US Pharmacopeial 11 Convention? 12 MS. PARFITT: Objection. Form. 13 THE WITNESS: I was not specifically 14 aware of that. I don't know what their specifications 15 are. 16 BY MR. JAMES: 17 Q. Did Plaintiffs' counsel provide to you those 18 specifications? 19 A. Not that I recall. 20 Q. Did you know that the specifications provide 21 mechanisms to test for the absence of asbestos? 22 MS. PARFITT: Objection. Form. 23 THE WITNESS: I have already stated 24 that I -- I don't know what those specifications are. 25</p>	<p>1 BY MR. JAMES: 2 Q. Dr. Moorman, if you could turn to the second 3 page of the letter. Is this the letter that you've 4 seen before, Dr. Moorman? 5 A. Yes, it is. 6 Q. And do you see that, in the section entitled 7 "Chemistry Findings," there's a discussion there by 8 the FDA pertaining to asbestos; correct? 9 A. Yes, I see that. 10 Q. And do you see that at the bottom of the 11 letter, the very last sentence, the FDA says 12 (as read): 13 "You have not provided evidence 14 that asbestos-contaminated 15 talc-containing cosmetic products 16 are currently being marketed, 17 since the data submitted is almost 18 40 years old." 19 Do you see that? 20 A. I do see that. 21 Q. Okay. And you said that you have reviewed 22 this letter in its entirety before? 23 A. I have read it, yes. 24 Q. Do you have any reason to quarrel with the 25 scientists at the FDA that have looked at the issue of</p>

22 (Pages 82 to 85)

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<p>1 asbestos contamination in talcum powder products?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: I don't know who those</p> <p>4 scientists are. I don't know any scientists at the</p> <p>5 FDA who would have done -- would have done this. I --</p> <p>6 so I can't say that I have a quarrel with them because</p> <p>7 I don't know them.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. Do you have any opinions about the type of</p> <p>10 asbestos that is alleged to contaminate talcum powder</p> <p>11 products?</p> <p>12 A. I am certainly aware that there are different</p> <p>13 types of asbestos. Again, from a health perspective,</p> <p>14 there is no safe form of asbestos. So if there are</p> <p>15 different types, it really doesn't make a lot of</p> <p>16 difference in terms of the potential health effects.</p> <p>17 MR. JAMES: Object to the nonresponsive</p> <p>18 portion.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Do you intend to offer any opinions about the</p> <p>21 type of asbestos that Plaintiffs contend contaminates</p> <p>22 talcum powder products?</p> <p>23 A. No, I am not going to specifically address</p> <p>24 the types of asbestos in talcum powder products.</p> <p>25 Q. Do you hold the opinion that asbestos causes</p>	<p>1 Did you form your opinions about asbestos</p> <p>2 and talcum powder that are contained within your MDL</p> <p>3 report after being retained as an expert?</p> <p>4 MS. PARFITT: Object to form.</p> <p>5 THE WITNESS: I -- it is often -- has</p> <p>6 often been reported in the literature that talcum</p> <p>7 powder contained asbestos prior to 1976, and that</p> <p>8 products produced after that did not contain asbestos.</p> <p>9 And as I became involved in this litigation,</p> <p>10 I was made aware of and discovered some of the</p> <p>11 articles that showed that talcum powder products after</p> <p>12 1976 contained asbestos.</p> <p>13 And so my opinion was that -- my opinion</p> <p>14 that asbestos in current or recently marketed talcum</p> <p>15 powder products could explain -- was part of the</p> <p>16 biological mechanism by which exposure to talcum</p> <p>17 powder, that was -- that was formed as I became aware</p> <p>18 of more of the available information, when I became</p> <p>19 involved in this litigation.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. Setting aside the issue of asbestos in talcum</p> <p>22 powder, do you believe that asbestos is a cause of</p> <p>23 ovarian cancer?</p> <p>24 A. Yes, I do.</p> <p>25 Q. How many studies have explored the link</p>
Page 87	Page 89
<p>1 ovarian cancer?</p> <p>2 A. Yes.</p> <p>3 Q. Do you hold the opinion that exposure to</p> <p>4 asbestos through use of talcum powder products causes</p> <p>5 ovarian cancer?</p> <p>6 A. My opinion is based on exposure to talcum</p> <p>7 powder products and whatever is contained within them.</p> <p>8 And so if there is asbestos within talcum powder</p> <p>9 products, which we have some evidence to suggest that</p> <p>10 that is the case, then that provides a potential</p> <p>11 biological mechanism by which talcum powder products</p> <p>12 could cause ovarian cancer.</p> <p>13 Q. The opinion that you have pertaining to</p> <p>14 asbestos and ovarian cancer, did you form that opinion</p> <p>15 in the context of litigation?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 THE WITNESS: I'm not sure how -- could</p> <p>18 you perhaps restate the question?</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Absolutely.</p> <p>21 A. I'm not sure --</p> <p>22 Q. Absolutely.</p> <p>23 A. -- what you're asking.</p> <p>24 Q. Did you form the opinion that -- did you</p> <p>25 form -- let me start over.</p>	<p>1 between asbestos and ovarian cancer?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: In terms of epidemiologic</p> <p>4 literature, there have been a couple of meta-analyses;</p> <p>5 and the exact number, I don't have that off the top of</p> <p>6 my head, but I want to say approximately a dozen</p> <p>7 studies.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. Did you review the entire body of literature</p> <p>10 looking at a purported link between asbestos and</p> <p>11 ovarian cancer?</p> <p>12 MS. PARFITT: Objection. Form.</p> <p>13 THE WITNESS: I know that I looked at</p> <p>14 the meta-analyses. I looked at some data from IARC,</p> <p>15 and I believe that I have looked in some degree at,</p> <p>16 I think, all of the epidemiologic studies about</p> <p>17 asbestos and ovarian cancer.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. So did you look at all of the studies that</p> <p>20 are discussed in the IARC monograph?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 THE WITNESS: I have -- the IARC</p> <p>23 monograph, as they typically do, they look at many of</p> <p>24 the animal studies, some of the laboratory studies.</p> <p>25 I have not looked at all of them. I have looked at</p>

23 (Pages 86 to 89)

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<p>1 the epidemiologic studies, which, again, is my area of 2 expertise. 3 BY MR. JAMES: 4 Q. And we're speaking currently about the IARC 5 monograph on asbestos; correct? 6 A. Correct. 7 Q. On page 34 of your report, if that you have 8 handy, Dr. Moorman -- actually, I think I have the 9 wrong page number. Give me one second. 10 Okay. It's actually page 35. My apologies. 11 And you see -- I'm looking at the first -- 12 the top paragraph. And you state in the second 13 sentence -- do you see where I am? It starts with 14 "IARC"? 15 A. Yes. 16 Q. Says (as read): 17 "IARC has stated that a causal 18 association between exposure to 19 asbestos and cancer of the ovary 20 was clearly established based on 21 strongly positive cohort mortality 22 studies of women with occupational 23 exposure to asbestos, as well as 24 studies of women with 25 environmental exposure to</p>	<p>1 Dr. Moorman. 2 A. Yes. 3 Q. Actually, 256 is where it carries into. And 4 on page 256, there's a section entitled "syntheses." 5 Do you see where I am, Dr. Moorman? 6 A. Yes. 7 Q. Okay. And if you look at the right-hand 8 column, it's the first full paragraph in the middle of 9 the page. 10 A. Yes. 11 Q. And there, the IARC states that (as read): 12 "The working group noted that a 13 causal association between 14 exposure to asbestos and cancer of 15 the ovary was clearly established 16 based on five strongly positive 17 cohort mortality studies of women 18 with heavy occupational exposure 19 to asbestos." 20 Do you see that? 21 A. Yes. 22 Q. Okay. And so the IARC then goes on to say, 23 in the next sentence, that the conclusion (as read): 24 "Received additional support from 25 studies showing that women and</p>
Page 91	Page 93
<p>1 asbestos." 2 A. Yes. 3 Q. Do you see where I was reading? 4 A. Yes. 5 Q. To be clear, Dr. Moorman, that's not 6 precisely how IARC has stated that, is it? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: I -- 9 BY MR. JAMES: 10 Q. I'm sorry, Doctor. 11 If I may, Dr. Moorman, I'll just provide you 12 a copy. Is that okay? 13 A. Okay. 14 Q. I'm going to mark as Exhibit 14 a copy of 15 the -- what we're referring to as the asbestos 16 monograph that's 100C. 17 (Exhibit No. 14 was marked for identification.) 18 MS. PARFITT: Mr. James, just for the 19 record, that's not the entire 100C monograph, is it? 20 MR. JAMES: Thank you. Thank you. Let 21 me clarify. This is excerpts of -- Exhibit 14 is 22 excerpts of the monograph. 23 MS. PARFITT: Thank you. 24 BY MR. JAMES: 25 Q. Okay. And if we turn to page 254,</p>	<p>1 girls with environmental, but not 2 occupational exposure to asbestos, 3 had positive, but nonsignificant, 4 increases in both ovarian cancer 5 incidence and mortality." 6 Do you see that? 7 A. Yes. 8 Q. And so the IARC's conclusion here with 9 respect to asbestos and ovarian cancer. 10 Again, this conclusion is being made outside 11 the context of talcum powders; correct? 12 A. Right. This is based on asbestos exposure. 13 Q. And the way that IARC has structured this 14 paragraph is that they have said that they've based 15 their conclusion on the occupational studies; correct? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: Yes. 18 BY MR. JAMES: 19 Q. And then they do note the additional support 20 after that sentence; correct? 21 MS. PARFITT: Objection to form. 22 THE WITNESS: Yes. 23 BY MR. JAMES: 24 Q. Okay. And just to be clear, the IARC here 25 acknowledges that the non-occupational studies report</p>

24 (Pages 90 to 93)

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<p>1 nonstatistically significant associations; correct?</p> <p>2 A. They note "positive, though nonsignificant</p> <p>3 increases."</p> <p>4 Yes, that's what it states.</p> <p>5 Q. And if you turn with me to page 280 of the</p> <p>6 same monograph, Dr. Moorman, with respect to talcum</p> <p>7 powder, specifically, on the right-hand column of</p> <p>8 page 280, it's the third full paragraph down, the IARC</p> <p>9 monograph states (as read):</p> <p>10 "The association between exposure</p> <p>11 to talc, potential or retrograde</p> <p>12 translocation to the ovarian</p> <p>13 epithelium, and the development of</p> <p>14 an ovarian cancer is</p> <p>15 controversial."</p> <p>16 Do you see where I was reading that?</p> <p>17 A. I do see that.</p> <p>18 Q. So in the same monograph where they're</p> <p>19 talking about asbestos and ovarian cancer in general,</p> <p>20 the IARC calls out the issue of talcum powder as a</p> <p>21 controversial association; correct?</p> <p>22 MS. PARFITT: Objection. Form.</p> <p>23 THE WITNESS: That's what it states,</p> <p>24 yes.</p> <p>25</p>	<p>1 A. Yes.</p> <p>2 Q. The IARC has not concluded that the presence</p> <p>3 of asbestos in talc powders renders such powders as</p> <p>4 carcinogenic, has it?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: I can't recall if they</p> <p>7 have made that conclusion or not.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. You understand that when the IARC separately</p> <p>10 assessed talcum powders in the other monograph that</p> <p>11 we're talking about, they classified perineal talc use</p> <p>12 as a 2B do you know that?</p> <p>13 MS. PARFITT: And you're referring to</p> <p>14 the 2010 monograph?</p> <p>15 MR. JAMES: Yes, and I think that's</p> <p>16 what I said, and if I didn't, my apologies.</p> <p>17 THE WITNESS: Yes, to be a possible</p> <p>18 carcinogenic.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Okay. And by designating perineal talc use</p> <p>21 as a 2B, the IARC is not concluding that it is, in</p> <p>22 fact, a carcinogenic; correct?</p> <p>23 A. What they are concluding is that it is a</p> <p>24 possible carcinogen.</p> <p>25 Q. IARC has multiple classifications; correct?</p>
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<p>1 BY MR. JAMES:</p> <p>2 Q. Did you cite that conclusion in your report?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: I did not specifically</p> <p>5 cite this, because, you know, again, this was a</p> <p>6 conclusion made IARC 2010, and additional data has</p> <p>7 accumulated. And so I think that we're seeing that if</p> <p>8 they had -- you know, of course, I have no way of</p> <p>9 knowing what they would conclude, but I think that, in</p> <p>10 light of additional evidence that has arisen since the</p> <p>11 time that this report was written, a different</p> <p>12 conclusion could have been reached.</p> <p>13 MR. JAMES: Okay. And I object to the</p> <p>14 nonresponsive portion of that answer.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. And for purposes of the record, Dr. Moorman,</p> <p>17 the monograph that we're looking at here together was</p> <p>18 published in 2012; correct?</p> <p>19 A. That is correct.</p> <p>20 Q. I think that you're probably thinking of the</p> <p>21 other monograph, which is the 2010 monograph; correct?</p> <p>22 When you said 2010?</p> <p>23 A. Well, I was looking at what was stated in</p> <p>24 that paragraph.</p> <p>25 Q. Fair enough. Fair enough.</p>	<p>1 A. That is correct.</p> <p>2 Q. If they characterize -- if they -- if they</p> <p>3 characterize something as a carcinogen, they label it</p> <p>4 as a Group 1; correct?</p> <p>5 A. That is correct.</p> <p>6 Q. If they characterize something as a probable</p> <p>7 carcinogen, they label it a 2A; correct?</p> <p>8 A. That is correct.</p> <p>9 Q. And if they characterize something as a</p> <p>10 possible, it's a 2B; correct?</p> <p>11 A. That is correct.</p> <p>12 Q. And the IARC has settled on 2B with talc --</p> <p>13 and with perineal talc use; correct?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 THE WITNESS: Once again, at the time</p> <p>16 of the report, that's what they decided on.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. The opinions that you're offering in</p> <p>19 litigation in this MDL report are contrary to those</p> <p>20 reached by IARC; correct?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 THE WITNESS: No. I don't think that</p> <p>23 they are contrary. I think possible carcinogen --</p> <p>24 they are not saying it is not a carcinogen; they're</p> <p>25 saying a possible carcinogen.</p>

25 (Pages 94 to 97)

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<p>1 And I -- my report, with the additional 2 information that has been published since the time 3 that this report was done, I think that it strengthens 4 the conclusions. And that's why I felt comfortable 5 saying that it is a cause of ovarian cancer. 6 BY MR. JAMES: 7 Q. And so what you're saying is different than 8 what the IARC said in 2010; correct? 9 MS. PARFITT: Objection. Misstates her 10 testimony. Asked and answered. 11 THE WITNESS: I'm saying that there is 12 additional evidence that has arisen, and it 13 strengthens the -- it strengthens the evidence for the 14 association between talc and ovarian cancer. 15 BY MR. JAMES: 16 Q. And in 2010, IARC did not determine that 17 perineal talc use was carcinogenic; correct? 18 A. They said -- 19 MS. PARFITT: Objection. Misstates 20 testimony. 21 THE WITNESS: -- it was a possible 22 carcinogen. 23 MR. JAMES: I didn't misstate any 24 testimony. I didn't state anything about her 25 testimony. I asked a question.</p>	<p>1 MR. MIZGALA: There's a big difference. 2 MR. JAMES: Let's just move on. 3 MS. PARFITT: I didn't say 4 "peritoneal." That may be what the court reporter -- 5 And, Sophie, the record should reflect that 6 when we are saying -- for the most part, when someone 7 wants to say something, it's "perineal" -- 8 MR. JAMES: May we continue? 9 MS. PARFITT: I appreciate it. Thank 10 you. 11 I just want to help the court reporter out, 12 Scott. I'm sure you want a very clear record. 13 And, James, thank you very much for making 14 sure it is clear. 15 So, Sophie, thank you. When we say 16 "perineal," we mean "perineal." Not your fault at 17 all. 18 Thank you. 19 MR. JAMES: Are we good? 20 MS. PARFITT: We are so good. 21 BY MR. JAMES: 22 Q. In 2010, the IARC declared talc -- perineal 23 talc a 2B; correct? 24 A. That is correct. 25 Q. Okay. In 2010, the evidence that was before</p>
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<p>1 MS. PARFITT: You actually 2 misrepresented her answer in your question. That was 3 my objection. You can go ahead. 4 MR. JAMES: If you'd like to read the 5 realtime, I didn't say anything about what she 6 testified to. I asked a question -- 7 MS. PARFITT: You said, "In 2010" -- 8 (Over-speaking.) 9 MR. JAMES: But if you want to continue 10 to do that all day -- 11 MS. PARFITT: -- "IARC did not 12 determine that peritoneal [sic] talc was carcinogenic; 13 correct?" 14 Just before that, she had said that it was 15 carcinogenic. 16 MR. JAMES: But I wasn't misstating her 17 testimony. 18 MS. PARFITT: Well, when you say that, 19 and she answered the question before that that's not 20 what IARC said, and then you say that is what IARC 21 says, you are misstating her testimony. 22 MR. MIZGALA: It's "perineal," not 23 "peritoneal." 24 MR. JAMES: Let's just move on. If you 25 continue to --</p>	<p>1 the IARC -- was the evidence at that time sufficient 2 for IARC to have said something more than 2B? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I'm not quite sure. 5 BY MR. JAMES: 6 Q. You want me to rephrase? 7 A. Yes, if you wouldn't mind. 8 Q. You alluded to evidence that has -- and if 9 I'm misstating your testimony, Ms. Parfitt, please 10 object, because now I actually am talking about your 11 testimony. 12 A. Okay. 13 Q. But you alluded earlier that evidence has 14 developed since the 2010 monograph; correct? 15 A. Right. 16 Q. And so my question is, in your expert 17 assessment in 2010, when the IARC declared perineal 18 talc use to be a 2B, was the evidence at that snapshot 19 in time sufficient to support something more than 2B, 20 less than 2B, or did the IARC get it right? 21 MS. PARFITT: Objection. Form. 22 THE WITNESS: I -- I think that their 23 statement that it is a possible carcinogen -- I don't 24 know if you can -- you know, possible versus probable, 25 it's -- I don't know that there is any checklist to</p>

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<p>1 say this level of evidence would lead it to possible 2 versus probable. 3 And so to say whether or not they got it 4 right, I don't know how to answer that question. 5 I think that they certainly are indicating that there 6 was evidence indicating a problem, and now we have 7 more evidence that strengthens the -- I think there's 8 greater evidence that talc can cause ovarian cancer. 9 BY MR. JAMES: 10 Q. If someone had asked you to assess the body 11 of scientific and medical literature in 2010 on the 12 claim that talcum powder products cause ovarian 13 cancer, would you have opined in 2010 that the 14 evidence was sufficient to state that talcum powder 15 products generally cause ovarian cancer? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: I think that it is 18 impossible to say with certainty what -- at that point 19 in time what would I have opined? I think that, as we 20 are well aware, the body of literature has continued 21 to grow over time. I think that it has only 22 strengthened over time. At what point would I have 23 been able to opine that talc is a cause of ovarian 24 cancer? I can't pinpoint that exactly. 25</p>	<p>1 MS. PARFITT: Objection to form. 2 THE WITNESS: I -- when I look at some 3 of the studies, there are limitations, as there are 4 with -- I would say, with any study of humans and 5 cancer. 6 One of the things that comes to mind as a 7 possible limitation is that, in the occupational 8 studies, the cohorts are relatively small for looking 9 at cancer outcomes. So in many -- maybe the 10 majority -- of them, they had a few hundred people in 11 the cohort; and, when you looked at the expected 12 versus the observed number of cases, we're talking 13 about a handful of cases. 14 So it might be, you know, two or three 15 observed cases versus .6 expected or something like 16 that. 17 So that is a limitation of all of -- as 18 I recall, all of the occupational cohort studies that 19 the sample cites of the cohort. 20 BY MR. JAMES: 21 Q. Would you also acknowledge that another 22 limitation to that body of literature is the fact that 23 it's in the occupational context? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: I don't necessarily</p>
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<p>1 BY MR. JAMES: 2 Q. And when you say in 2010 IARC declared talc a 3 2B, I think the phrasing that you used was that they 4 were saying that there was, quote, a problem. 5 Is that what you said? 6 A. I think that I said something to that effect. 7 Q. Okay. You understand that the IARC's 8 classification system does have a checklist of sorts 9 to determine if something is a 1, a 2A, or a 2B; 10 correct? Or a 3 and so on and so forth. 11 A. I am not familiar with the exact checklist. 12 Yes. 13 Q. Do you understand that, if IARC declares 14 something a 2B, it's concluding that chance, bias, and 15 confounding cannot be ruled out? Did you know that? 16 A. Again, off the top of my head, I cannot 17 recall exactly what are their -- you know, as you put 18 it, what is their checklist. 19 Q. Returning now back to the body of literature 20 on asbestos and ovarian cancer, you have testified 21 that you have reviewed that body of literature; 22 correct? 23 A. Yes. 24 Q. Do you recognize any limitations to that body 25 of literature?</p>	<p>1 consider that a limitation. That is where people had 2 exposure to this -- to asbestos in an occupational 3 setting. So if you want to look at the health effects 4 of that exposure, that's exactly where you would do 5 the study. 6 BY MR. JAMES: 7 Q. Do you agree that the body of literature in 8 the occupational context, which looks at exposure to 9 asbestos in the occupational setting, is different 10 than the allegation that exposure to contaminated 11 talcum powder products causes ovarian cancer? 12 A. The -- I agree that there is some difference 13 in the exposure, but it's part of the body of 14 literature. It's -- people exposed in this way, they 15 are at increased risk for ovarian cancer. So they may 16 have different levels of exposure, different routes of 17 exposure, but it's all part of the body of literature. 18 Q. You would agree that someone that's exposed 19 to asbestos-containing products in a factory 20 environment for a full workday is experiencing a 21 different level of exposure to someone who is using 22 allegedly contaminated asbestos talcum powder 23 products? 24 MS. PARFITT: Objection. Form. 25</p>

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<p>1 BY MR. JAMES: 2 Q. Let me rephrase that, because I jumbled that 3 up. 4 Would you agree that the level of exposure 5 that someone would experience in the occupational 6 setting to asbestos products is qualitatively 7 different than what Plaintiffs are alleging in this 8 case, which is exposure to talcum powder products that 9 are allegedly contaminated with asbestos? 10 A. I acknowledge that the exposures are 11 different. It's how they are applied -- or, you know, 12 the -- you know, we're talking about exposure to the 13 genital area when we're talking about talcum powder 14 products that may contain asbestos, where we would not 15 expect to have genital exposure of asbestos in an 16 occupational setting. 17 So, yes, there are differences. 18 Q. Do you acknowledge another limitation in the 19 body of literature that IARC looked at to be 20 misclassification? 21 A. In epidemiology, we -- we recognize that 22 there is likely to be misclassification in any 23 epidemiologic study that you do. This is not a 24 situation like with laboratory studies of animals 25 where you can control every exposure, measure it very</p>	<p>1 meta-analysis before; correct? 2 A. I have. 3 Q. You don't have any discussion of the Reid 4 paper in your report; correct? 5 A. I don't -- I don't believe I do. 6 Q. Do you understand that the Reid paper 7 conflicts in part with the claim that asbestos is a 8 cause of ovarian cancer? 9 MS. PARFITT: Objection. 10 THE WITNESS: I know what they -- what 11 these authors concluded. 12 BY MR. JAMES: 13 Q. And if you look with me on page 1294, 14 Dr. Moorman, in the "conclusions" section, you see at 15 the bottom of that paragraph, with the sentence 16 beginning with the word "however" -- it's sort of 17 three-fourths of the way down -- the authors state 18 (as read): 19 "However, the authors of this 20 article suggest that the IARC 21 decision to determine asbestos 22 exposure as a cause of ovarian 23 cancer was premature and not 24 wholly supported by the evidence." 25 Do you see where I read that?</p>
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<p>1 accurately. 2 So some potential misclassification is 3 possible, as it is in any epidemiologic study. 4 Q. And the issue of misclassification has been 5 specifically acknowledged in this body of literature; 6 correct? 7 MS. PARFITT: Objection to form. 8 THE WITNESS: Can you be more specific 9 about which misclassification you're referring to? 10 BY MR. JAMES: 11 Q. Sure. So what I'm referring to is 12 misclassification of disease. 13 Do you -- do you recall that, in this body 14 of literature, there is discussion that, given the 15 small number of cases which you described earlier, 16 misclassification -- the potential for disease 17 misclassification is a limitation to this body of 18 literature? 19 A. I am aware that that is an issue that has 20 been discussed in this literature, yes. 21 MR. JAMES: And I'm going to mark as 22 Exhibit No. 15 the Reid paper. 23 (Exhibit No. 15 was marked for identification.) 24 BY MR. JAMES: 25 Q. And, Dr. Moorman, you've seen this Reid</p>	<p>1 A. I do see that. 2 Q. Okay. And so you acknowledge here that the 3 authors of this paper have called into question the 4 IARC decision; correct? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: I see what they have 7 stated here, that -- 8 BY MR. JAMES: 9 Q. And -- 10 A. -- that is their opinion, yes. 11 Q. Excuse me, Doctor. My apologies. 12 A. Yes. 13 Q. And, again, this paper is assessing the 14 IARC's conclusion about asbestos and ovarian cancer in 15 general; correct? 16 MS. PARFITT: Objection. Form. 17 BY MR. JAMES: 18 Q. It's not -- this article isn't pertaining to 19 the issue of alleged asbestos contamination in talcum 20 powder products, is it? 21 A. Right. This is focused just on asbestos and 22 ovarian cancer. 23 Q. And if you look at the bottom of that -- the 24 very last sentence in that paragraph, you see where 25 the authors there discuss the potential problem of</p>

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<p>1 misclassification?</p> <p>2 A. I'm sorry, where are you?</p> <p>3 Q. It's the very last sentence, Doctor.</p> <p>4 A. Yes, I see what is written there.</p> <p>5 Q. So this article conflicts with your</p> <p>6 litigation opinion; correct?</p> <p>7 MS. PARFITT: Objection. Form.</p> <p>8 THE WITNESS: This reflects the opinion</p> <p>9 of these authors. There was another meta-analysis of</p> <p>10 asbestos and ovarian cancer that I believe was</p> <p>11 published in the same year. And as I recall, the</p> <p>12 conclusions of those authors, while acknowledging</p> <p>13 potential misclassification of disease, they felt like</p> <p>14 the evidence was adequate to rule that out as a</p> <p>15 possible source of bias that would explain the</p> <p>16 association that was observed.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. And you're speaking of the Camargo article,</p> <p>19 I believe?</p> <p>20 A. Yes.</p> <p>21 Q. And have you separately assessed the issue of</p> <p>22 misclassification and whether, in your mind, that</p> <p>23 presents a significant enough problem to call into</p> <p>24 question the IARC conclusions?</p> <p>25 MS. PARFITT: Objection. Form.</p>	<p>1 Q. Did you review those articles?</p> <p>2 A. I did look at them, and as I recall, almost</p> <p>3 all of those -- the miners and -- almost all of the</p> <p>4 miners, and probably the millers, they were focusing</p> <p>5 primarily on males who were the people who were mostly</p> <p>6 involved in that type of work.</p> <p>7 Q. You would agree with me that if talcum</p> <p>8 powder, that is used in cosmetic talc products, is, in</p> <p>9 fact, contaminated with asbestos, then you would</p> <p>10 expect to see increased cancer incidence rates, for</p> <p>11 example, of mesothelioma, in cosmetic talc miners and</p> <p>12 millers; correct?</p> <p>13 MS. PARFITT: Objection. Form.</p> <p>14 THE WITNESS: I wouldn't be surprised</p> <p>15 to see that, yes.</p> <p>16 BY MR. JAMES:</p> <p>17 Q. And did you know that that body of literature</p> <p>18 reports no increased cancer incidence in talc miners</p> <p>19 and millers?</p> <p>20 A. It has been a while since I have looked at</p> <p>21 those papers, so I don't remember exactly what they</p> <p>22 reported.</p> <p>23 Q. And those papers are not discussed in your</p> <p>24 report; correct?</p> <p>25 A. Once again, I was focusing primarily on</p>
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<p>1 THE WITNESS: Let me read your...</p> <p>2 I believe that I was convinced by the</p> <p>3 information presented in the Camargo article that</p> <p>4 I don't think that misclassification was enough of a</p> <p>5 problem to change the conclusion.</p> <p>6 BY MR. JAMES:</p> <p>7 Q. Are you familiar with -- did you undertake a</p> <p>8 Bradford Hill analysis of the literature on asbestos</p> <p>9 and ovarian cancer to reach the conclusion that</p> <p>10 asbestos is a cause of ovarian cancer?</p> <p>11 A. I didn't -- did not do the Bradford Hill</p> <p>12 analysis as I did with the talcum powder products and</p> <p>13 ovarian cancer. I felt like it was pretty well</p> <p>14 accepted.</p> <p>15 Q. Did you consider a body of literature</p> <p>16 commonly referred to as the "miners and millers</p> <p>17 studies"?</p> <p>18 A. Please -- I'm sorry. When you talk about the</p> <p>19 miners and millers studies, I'm not sure that I'm on</p> <p>20 the same page with you.</p> <p>21 Q. Are you familiar -- are you aware of the fact</p> <p>22 that there's a body of literature that has looked at</p> <p>23 cancer incidence rates in miners and millers of talc?</p> <p>24 A. Yes, I am aware of some of those articles.</p> <p>25 Yes.</p>	<p>1 ovarian cancer. And as many of these were on male</p> <p>2 subjects, I had looked at them, but they were of</p> <p>3 somewhat lesser importance to my review.</p> <p>4 Q. If --</p> <p>5 MS. PARFITT: I don't want to</p> <p>6 interrupt, and maybe a few follow-up questions. We're</p> <p>7 probably into about an hour and 20 minutes or so. But</p> <p>8 I don't want to interrupt your flow either.</p> <p>9 MR. JAMES: I can finish up in a few,</p> <p>10 or if you need a break now, we can take it now.</p> <p>11 THE WITNESS: Let's finish up in a few.</p> <p>12 MR. JAMES: And when I say "finish up,"</p> <p>13 I just mean this line. I apologize for that. That</p> <p>14 was misleading, I think.</p> <p>15 Sure. Give me a couple more, and then we'll</p> <p>16 take a break.</p> <p>17 THE WITNESS: Yeah, we can go a few</p> <p>18 more minutes.</p> <p>19 MS. PARFITT: Thank you, Scott.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. If asbestos-contaminated talcum powder</p> <p>22 products have existed on the market for some period of</p> <p>23 time, wouldn't you expect to find higher incidence</p> <p>24 rates of other cancers of talcum powder users?</p> <p>25 MS. PARFITT: Objection. Form.</p>

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<p style="text-align: right;">Page 114</p> <p>1 THE WITNESS: It depends. 2 BY MR. JAMES: 3 Q. For example -- oh, I'm sorry. I thought you 4 were done. 5 A. I am done. Go ahead. 6 Q. For example, if asbestos has contaminated 7 talcum powder products for some period of time, 8 wouldn't you expect to see higher rates of 9 mesothelioma in users of cosmetic talcum powder 10 products? 11 A. You know, mesothelioma is an exceedingly rare 12 cancer, and I don't know -- I don't know to what 13 extent it has been -- talcum powder products -- 14 cosmetic talcum powder products has been examined as a 15 risk factor for that. 16 Q. Are you aware of any data showing that users 17 of cosmetic talcum powder products are at greater risk 18 of mesothelioma, asbestosis, or any other 19 asbestos-related diseases? 20 MS. PARFITT: Objection. Form. 21 THE WITNESS: I can't think of that 22 data right offhand, no. 23 MR. JAMES: Okay. And how about now 24 for a break? 25 THE WITNESS: Okay.</p>	<p style="text-align: right;">Page 116</p> <p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: I considered it as part 3 of the constituents of the talcum powder products. My 4 overall opinion is based on exposure to talcum powder 5 products and whatever constituents are in there, 6 including the fibrous talc. 7 BY MR. JAMES: 8 Q. Given that you have opined in your MDL report 9 for the first time on fibrous talc and did not provide 10 that opinion in the Ingham case, can you tell me what 11 you're basing your opinion on with regard to the 12 fibrous talc? 13 MS. PARFITT: Objection. 14 Hey, Scott, if I can ask -- I'm sorry, it 15 isn't rolling. Is there some reason? I don't want to 16 interrupt. We'll deal with it. 17 THE COURT REPORTER: I can come over 18 and do it, but we'll have to go off. 19 MS. PARFITT: Sorry about that. 20 THE VIDEOGRAPHER: Going off the record 21 at 12:40 p.m. 22 (Off the record.) 23 THE VIDEOGRAPHER: Back on record at 24 12:41 p.m. 25</p>
<p style="text-align: right;">Page 115</p> <p>1 MS. PARFITT: Thank you. 2 THE VIDEOGRAPHER: Going off record at 3 11:45 a.m. 4 (Recess taken from 11:45 a.m. to 12:39 p.m.) 5 THE VIDEOGRAPHER: Back on record at 6 12:39 p.m. 7 BY MR. JAMES: 8 Q. Dr. Moorman, you include in your MDL report 9 references to "talc occurring in the fibrous habit." 10 Do you recall referring to that in your 11 report? 12 A. Yes, I do. 13 Q. That terminology is new to the MDL for you, 14 isn't it? 15 MS. PARFITT: Objection. Form. 16 BY MR. JAMES: 17 Q. I'll clarify. 18 A. Please. Please do. 19 Q. You did not -- in your Ingham testimony, 20 where you provided your opinions in the Ingham case, 21 you did not refer to "fibrous talc," did you? 22 A. No, I don't believe I did. 23 Q. So that -- sorry. 24 So that's a new component of your opinion in 25 the MDL?</p>	<p style="text-align: right;">Page 117</p> <p>1 BY MR. JAMES: 2 Q. Dr. Moorman, before the quick break -- I'll 3 just restate the question. 4 A. Okay. 5 Q. So what do you base your opinions on with 6 regard to fibrous talc? 7 A. Okay. My opinion, I guess, is -- again, it's 8 always been based on the constituents of the talcum 9 powder products. And so maybe clarifying based on 10 maybe further reading on the constituents of, like, 11 asbestiform talc, that this again contributes to the 12 biological plausibility of it, that this is another 13 potential constituent of the talcum powder product 14 that could contribute to ovarian cancer risk. 15 Q. So one component of your opinion is that 16 there is fibrous talc in talcum powder products; 17 correct? 18 A. Yes. 19 Q. Okay. And given that that is a new opinion, 20 I am attempting to source the bases for that opinion. 21 Are the opinions that you have about the 22 presence of fibrous talc in talcum powder products 23 based upon the same materials that you rely on for 24 your opinions about the presence of asbestos in talcum 25 powder products?</p>

30 (Pages 114 to 117)

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<p>1 MS. PARFITT: Objection. Form. As far 2 as a new opinion. 3 THE WITNESS: I'm sorry, let me read 4 that. 5 So my opinions about the presence of fibrous 6 talc in talcum powder products is based on some of the 7 same materials that have done analyses of talcum 8 powder products, yeah. 9 BY MR. JAMES: 10 Q. Would that include the Longo -- Dr. Longo 11 litigation testing? 12 A. I believe that he did make some mention of 13 that in his report, yes. 14 Q. And other -- would that include other 15 litigation reports that you reviewed? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: I'm -- precisely where 18 the information came from, that there is fibrous talc 19 in talcum powder products, I -- I don't recall exactly 20 where -- where I gleaned that information. 21 BY MR. JAMES: 22 Q. And did you -- did you ask counsel if there 23 was any information provided by Johnson & Johnson in 24 the talc litigation rebutting the claim that there's 25 fibrous talc present in the products?</p>	<p>1 BY MR. JAMES: 2 Q. Would you defer to others with regard to the 3 question of whether heavy metals are in the talcum 4 powder products? 5 A. I -- by deferring to others, okay, I clearly 6 do not do the analyses of those -- of those -- those 7 types of analyses myself, so I am relying on a report. 8 In this case, it was a report done by Dr. Crowley. 9 Q. Just to clarify, and Ms. Parfitt can correct 10 me if I'm wrong, but when you refer to Dr. Crowley's 11 report, are you referring to Dr. Crowley's report 12 about fragrances? 13 A. And I believe that it was not just 14 fragrances, but it was a number of substances that he 15 analyzed in that -- that he addressed in his analysis. 16 Q. Did you do any independent searching for 17 materials or scientific literature on the allegation 18 that heavy metals in cosmetic talc powders cause 19 ovarian cancer? 20 MS. PARFITT: Objection. 21 THE WITNESS: Okay. I'm reading your 22 question again. 23 No. I -- the -- what I looked at in regards 24 to heavy metals -- again, we have this report 25 indicating that these can be found in some talcum</p>
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<p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: No, I did not 3 specifically ask them for that information. 4 BY MR. JAMES: 5 Q. Have you relied on any epidemiology 6 substantiating a claim that fibrous talc is 7 carcinogenic? 8 A. I am not aware of any epidemiologic 9 literature that specifically addressed that question. 10 Q. Turning to your opinions on heavy metals, 11 Dr. Moorman, you have opined in your report about 12 chromium, nickel, and cobalt; correct? 13 A. Yes, I have. 14 Q. Yet your opinions in the MDL report about the 15 alleged presence of chromium, nickel, and cobalt in 16 talcum powder products is new in the sense that you 17 did not express that opinion in the Ingham case; 18 correct? 19 MS. PARFITT: Objection. Misstates her 20 testimony -- our testimony. 21 THE WITNESS: I think the gist of my 22 opinions are based on talcum powder products and 23 whatever constituents are in there; so talc, asbestos, 24 any fragrances or other contaminants that may be in 25 there. So it's based on the product.</p>	<p>1 powder products, and then again we have data 2 indicating that these heavy metals can cause certain 3 types of cancer. 4 So it contributes to the biological 5 plausibility that there are substances in the talcum 6 powder products that could lead to cancer. 7 BY MR. JAMES: 8 Q. With regard to opinions about the presence of 9 heavy metals in talcum powder products, did you ask to 10 see any information or materials presented in the talc 11 litigation by Johnson & Johnson as to that claim? 12 A. No, I did not. 13 Q. Did you do any separate analysis of the 14 talcum powder products to determine the presence of 15 heavy metals in these products? 16 A. I did not do any analyses of talcum powder 17 products. 18 Q. Do you have any knowledge concerning the 19 testing that is performed by Johnson & Johnson and 20 third parties with respect to constituent elements in 21 the products? 22 A. No. This is outside my area of expertise. 23 Q. Do you have any information about allowable 24 levels of constituent elements in the talcum powder 25 products?</p>

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<p>1 A. No, I do not.</p> <p>2 Q. Do you have any basis to believe that if</p> <p>3 talcum powder products exceeded allowable levels for</p> <p>4 constituent elements, that those products went to</p> <p>5 market?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 THE WITNESS: No, I -- I don't have any</p> <p>8 information in that regard.</p> <p>9 BY MR. JAMES:</p> <p>10 Q. Okay. Turning to -- with -- to your opinion</p> <p>11 on -- strike that.</p> <p>12 Do you hold the independent opinion that</p> <p>13 cadmium, chromium, and cobalt cause ovarian cancer?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 THE WITNESS: I do -- I am not aware of</p> <p>16 papers that have directly addressed those metals in</p> <p>17 relation to ovarian cancer risk. I am basing it more</p> <p>18 on the conclusions from IARC that they do have</p> <p>19 carcinogenic potential.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. And is the same true for nickel?</p> <p>22 A. Yes.</p> <p>23 Q. With regard to the alleged carcinogenicity of</p> <p>24 the constituent metal elements that you've identified</p> <p>25 in your report, did you consider anything other than</p>	<p>1 THE WITNESS: I -- I think that we do</p> <p>2 not have the data to specifically address that</p> <p>3 question specifically in regard to ovarian cancer.</p> <p>4 BY MR. JAMES:</p> <p>5 Q. With regard to the opinions you've expressed</p> <p>6 as to fragrances, is the sole basis of those opinions</p> <p>7 the value of work?</p> <p>8 A. That's the only document that I referred to.</p> <p>9 Q. And you understand --</p> <p>10 MR. JAMES: Ms. Parfitt, is it</p> <p>11 Dr. Crowley?</p> <p>12 MS. PARFITT: Dr. Crowley.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. Okay. Do you understand that Dr. Crowley is</p> <p>15 a paid expert in this litigation for the Plaintiffs?</p> <p>16 A. I do understand that.</p> <p>17 Q. Do you know if Dr. Crowley conducted any sort</p> <p>18 of risk assessment with regard to his calculations?</p> <p>19 A. I do not know that.</p> <p>20 Q. If Johnson & Johnson talcum powder products</p> <p>21 were not contaminated with asbestos, if you would</p> <p>22 accept that proposition from me, would you still hold</p> <p>23 the opinion that talcum powder products are a general</p> <p>24 cause of ovarian cancer?</p> <p>25 MS. PARFITT: Objection. Form.</p>
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<p>1 the IARC monograph that you cited?</p> <p>2 A. No, I did not.</p> <p>3 Q. Did the IARC monograph that you cited include</p> <p>4 any assertion that the presence of these metals in</p> <p>5 talcum powders rendered those powders carcinogenic?</p> <p>6 A. I do not believe so.</p> <p>7 Q. Did the IARC 2010 monograph on talc include</p> <p>8 any assertion that the presence of heavy metals in</p> <p>9 those powders supports the 2B conclusion?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 THE WITNESS: I don't recall any</p> <p>12 mention of heavy metals in that monograph.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. Returning back to fragrances, in your MDL</p> <p>15 report, you refer to a report by Crowley. Did I say</p> <p>16 that right?</p> <p>17 A. I've never met the man, so I don't know how</p> <p>18 it's pronounced, but yes, that's what I said.</p> <p>19 Q. And that's the report you identified for the</p> <p>20 basis of your fragrance opinions; correct?</p> <p>21 A. Yes.</p> <p>22 Q. Do you have -- do you hold the independent</p> <p>23 opinion that the fragrance ingredients in talcum</p> <p>24 powder products renders those products carcinogenic?</p> <p>25 MS. PARFITT: Objection.</p>	<p>1 You can answer.</p> <p>2 THE WITNESS: Okay. The opinion</p> <p>3 I formed is based primarily on the epidemiologic data;</p> <p>4 and the epidemiologic data is based on talcum powder</p> <p>5 products, whatever is contained in them. And in study</p> <p>6 after study, we see increased risk for ovarian cancer.</p> <p>7 So whatever is contained in the talcum powder products</p> <p>8 leads me to conclude that it can cause ovarian cancer.</p> <p>9 BY MR. JAMES:</p> <p>10 Q. And just to make sure that I understand your</p> <p>11 answer --</p> <p>12 A. Yes.</p> <p>13 Q. -- if the talcum powder products were not</p> <p>14 contaminated with asbestos, would you still reach the</p> <p>15 general cause opinion that you've offered in this</p> <p>16 case?</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: I am -- I think that I've</p> <p>19 answered the question that it's based on talcum powder</p> <p>20 products, whatever is contained them -- in them. If</p> <p>21 it is shown that there is no asbestos, that doesn't</p> <p>22 change the fact that these dozens of epidemiologic</p> <p>23 studies have led to the conclusion of increased risk.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. And does that same answer hold true if</p>

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<p>1 I asked you the same question with respect to heavy 2 metals, fibrous talc, and fragrance ingredients? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: Yes. I am basing my 5 opinion on the use of talcum powder products and 6 whatever are -- whatever their constituents are. 7 BY MR. JAMES: 8 Q. As a professional epidemiologist -- is that a 9 fair way to say it? 10 A. Yes. 11 Q. Okay. As a professional epidemiologist, part 12 of your day-in, day-out work is to look at literature 13 on purported associations and make conclusions about 14 the strengths or weaknesses of that literature; 15 correct? 16 A. Yes. 17 Q. And you have done that before you were 18 brought into the talc litigation on a variety of 19 different exposures or other things evaluated for 20 associations; correct? 21 A. That is correct. 22 Q. And setting aside the issue of talcum powder 23 products, have you ever before, in assessing other 24 exposures or other associations, relied upon company 25 documents to reach your conclusions?</p>	<p>1 BY MR. JAMES: 2 Q. On page 4 of your -- actually, it's page 5 of 3 your report, Dr. Moorman. You refer on the top of 4 that page, in the first full paragraph, to the 5 Schildkraut 2016 study; correct? 6 A. First paragraph? Yes, that is correct. 7 Q. And you say in that paragraph -- and if 8 you're looking at the same paragraph as I am -- you 9 say there that (as read): 10 "This was the first study of talc 11 use and ovarian cancer focused 12 exclusively on African-American 13 women." 14 Correct? 15 A. Yes, I do. 16 Q. And to be clear, Dr. Moorman, that study did 17 not look exclusively at talc use, did it? 18 A. No. The purpose of the African American 19 cancer epidemiology study was to look at the 20 epidemiology of ovarian cancer in African American 21 broadly. So we've looked at a number of exposures. 22 Q. And specific to the issue of powder, the 23 Schildkraut 2016 study -- and I guess is the 24 underlying study, the AACES -- looks at body powder, 25 not talc per se; correct?</p>
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<p>1 A. I -- I'm trying to think. 2 We have -- my colleagues and I have 3 published systematic reviews of oral contraceptive use 4 and ovarian cancer and other cancer risk. And as part 5 of that procedure -- this was through the Agency on 6 Healthcare Research and Quality, or AHRQ -- and as 7 part of that procedure trying to ensure that we have 8 all relevant documents, I believe that there was an 9 effort to see if there were any company document 10 studies that would be relevant to that systematic 11 review. 12 Q. What about any internal company testing 13 documents? Have you ever looked at any internal 14 company testing documents in assessing any association 15 that you've considered throughout your career? 16 A. No -- 17 MS. PARFITT: Objection. 18 THE WITNESS: -- I did not. 19 BY MR. JAMES: 20 Q. Have you ever considered any paid litigation 21 expert reports in assessing any other association that 22 you've looked at through your career? 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I -- I can't think of 25 another instance where I have done that.</p>	<p>1 A. That was how the question was asked in the 2 questionnaire, yes. 3 Q. Okay. And so the statements in your report 4 that state that the study looked at talc powder should 5 be clarified; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: I think to be absolutely 8 precise, we should have -- I should have said body 9 powder. But based on other literature, most body 10 powder use is talcum powder product use. So I agree, 11 I could have been more precise in my language there. 12 BY MR. JAMES: 13 Q. And you understand body powders are made up 14 of a variety of constituents; correct? 15 A. Yes. 16 Q. There are baby powders that are made of 17 things other than talc; correct? 18 A. I believe so, that there are cornstarch 19 powders as well. 20 Q. And there are deodorizing powders that are 21 made of things other than talc; correct? 22 A. I believe so, yes. 23 Q. And you know cornstarch, if there's a baby 24 powder made of cornstarch, that product does not 25 contain talc; correct?</p>

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<p>1 A. Yes.</p> <p>2 Q. Or -- I should clarify.</p> <p>3 If the version of the baby powder one is</p> <p>4 purchasing is labeled as a cornstarch product, it's</p> <p>5 cornstarch, not talc; correct?</p> <p>6 A. That is correct.</p> <p>7 Q. So the study participants in this study are</p> <p>8 not limited to talc users; correct?</p> <p>9 A. That is correct.</p> <p>10 Q. You also say in the report, in conjunction</p> <p>11 with these statements, that the study found a high</p> <p>12 prevalence of talc use; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And we're looking at the same paragraph,</p> <p>15 Dr. Moorman. And, again, to be clear, the study</p> <p>16 didn't find that. The study, instead, found a high</p> <p>17 prevalence of powder use; correct?</p> <p>18 MS. PARFITT: Objection.</p> <p>19 THE WITNESS: Again, once I -- as I</p> <p>20 acknowledged earlier, I could have been more precise</p> <p>21 in the language, that it's -- I think that it -- based</p> <p>22 on our knowledge of the sales and other studies that</p> <p>23 have specifically reported on the types of powder use,</p> <p>24 the majority of the powder use would have been talc.</p> <p>25</p>	<p>1 anywhere else in your report, that for any genital use</p> <p>2 of body powder with an interview date before 2014, the</p> <p>3 results were not statistically significant; correct?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 THE WITNESS: If you would give me just</p> <p>6 a moment to look through the report, I'd like to</p> <p>7 verify how I addressed that.</p> <p>8 I -- on page 23, I acknowledged that there</p> <p>9 was an attenuation of the odds ratio when comparing</p> <p>10 the women who were interviewed in the later time frame</p> <p>11 than in the earlier time frame.</p> <p>12 BY MR. JAMES:</p> <p>13 Q. Okay. And I'm looking at where you're</p> <p>14 looking, I believe, and it's the middle paragraph on</p> <p>15 page 23; correct?</p> <p>16 A. That is correct.</p> <p>17 Q. And there you say (as read):</p> <p>18 "The fact that the association was</p> <p>19 attenuated but not eliminated when</p> <p>20 considering the full study</p> <p>21 population suggested that the</p> <p>22 association was not due entirely</p> <p>23 to recall bias."</p> <p>24 Did I read that correctly?</p> <p>25 A. That is correct.</p>
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<p>1 BY MR. JAMES:</p> <p>2 Q. You're not offering opinions on the MDL</p> <p>3 litigation about cornstarch, are you?</p> <p>4 A. No, I am not.</p> <p>5 Q. And you understand that the body of</p> <p>6 epidemiological literature that has developed over the</p> <p>7 last several decades has included findings looking at</p> <p>8 talc powders versus cornstarch powders versus non-talc</p> <p>9 powders; correct?</p> <p>10 A. Some studies, yes, have looked at the</p> <p>11 different powders.</p> <p>12 Q. And your -- the Schildkraut 2016 study didn't</p> <p>13 undertake the effort to make that distinction, did it?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: I've already acknowledged</p> <p>16 that the question in the questionnaire just asked</p> <p>17 about body powder use.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. You state that this study found a</p> <p>20 statistically significant increase for risk among talc</p> <p>21 users; right?</p> <p>22 A. Yes. We're in the same paragraph. Right?</p> <p>23 Q. Yes, Doctor. Thank you.</p> <p>24 A. Yes.</p> <p>25 Q. But you did not know in this paragraph, or</p>	<p>1 Q. Okay. And, again, here you do not report --</p> <p>2 let me start over.</p> <p>3 The association for talc users before 2014</p> <p>4 date was not statistically significant; correct?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: Yes. The -- the odds</p> <p>7 ratio was elevated but not statistically significant.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. And you don't call that out in your report,</p> <p>10 do you?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 THE WITNESS: No. It's as it's</p> <p>13 written.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. And as it's written, it says, "The</p> <p>16 association was attenuated but not eliminated."</p> <p>17 That's the wording you used; correct?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. But if the association is not</p> <p>20 statistically significant, would you still refer to</p> <p>21 that association as attenuated and not eliminated? Is</p> <p>22 that the proper way to refer to it?</p> <p>23 A. If the association was eliminated, if there</p> <p>24 was no association, we would have had an odds ratio of</p> <p>25 1. We have an odds ratio of 1.19.</p>

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<p>1 It is -- I acknowledge that it was not 2 statistically significant, but it was not eliminated. 3 It was attenuated. I think that my statement in my 4 report is accurate. 5 Q. So for any epidemiologic study that has an 6 odds ratio that crosses 1 but is reported to be above 7 1 with the odds ratio crossing 1 -- do you understand 8 what I'm asking? -- would you refer to that as an 9 association, an null association, a not statistically 10 significant association? What terminology would you 11 use? 12 A. I would refer to it as a non-statistically 13 significant association. If the data show 19 percent 14 increased risk, it's not statistically significant. 15 Q. And by saying that, what you're saying is 16 that the odds ratio that -- could fall with any -- 17 within the range identified; correct? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: The -- when you report a 20 95 percent confidence interval, it gives a range of 21 values which is statistically compatible with what you 22 found. Like, if the study were repeated again with 23 other samples, you might find an odds ratio that was a 24 bit higher or a bit lower. 25 But I think that it's very important to make</p>	<p>1 with respect to talc? 2 A. If you -- I know you have it right in front 3 of you. So if I could see it, so I could report it 4 accurately. I think I know what I found, but that was 5 paper that was done ten years ago. 6 MR. JAMES: Okay. And, Dr. Moorman, 7 I'm marking as Exhibit 16 a paper entitled "Ovarian 8 Cancer Risk Factors in African-American and White 9 Women." 10 I'm handing you two copies to pass along. 11 (Exhibit No. 16 was marked for identification.) 12 THE WITNESS: Okay. So we reported on 13 talc use for white women and for African-American 14 women. Neither association was statistically 15 significant, again, particularly for the African 16 American, which can be a reflection of the relatively 17 small sample size for African-American women. It was 18 an odds ratio of 1.19; in the white women, it was 19 1.04. 20 BY MR. JAMES: 21 Q. And those two associations reported in your 22 paper in 2009 are not reported in your report, are 23 they? 24 A. I did not -- I do not believe that I reported 25 those specific odds ratios. Data from the</p>
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<p>1 the distinction between no association and no 2 statistically significant association. 3 BY MR. JAMES: 4 Q. But you didn't make that distinction in your 5 report? 6 MS. PARFITT: Objection. 7 THE WITNESS: You've asked the 8 question, and I've acknowledged that I did not address 9 statistical significance in that sentence. 10 BY MR. JAMES: 11 Q. On the same page of your report, if we go 12 back to page 5, you refer to a 2009 paper entitled 13 "Ovarian Cancer Risk Factors in African-American and 14 White Women"; correct? 15 A. Let me get to page 5. Which paragraph are 16 you -- 17 Q. So it's the second paragraph. In fact, you 18 refer to it here as the North Carolina Ovarian Cancer 19 Study; correct? 20 A. Right. Right. Okay. Yes. 21 Q. My apologies. I -- with -- in conjunction 22 that study, you published a paper in 2009; correct? 23 A. Right. Talc was not the primary focus of it, 24 but it was one of the risk factors that we looked at. 25 Q. And do you recall the results of that study</p>	<p>1 North Carolina ovarian cancer study was included in 2 the meta-analyses that I did describe. 3 Q. And with respect to odds ratio of 1.04 for 4 white women -- do you see that? Are we looking at the 5 same table together? Table 2? 6 A. Yes. 7 Q. Okay. And the 1.04 association there is very 8 close to the null; correct? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: Yes, it's close to 1. 11 BY MR. JAMES: 12 Q. And it has the odds ratio that crosses 1; 13 correct? The odds ratio range? Is that a fair way to 14 say it? 15 A. No. 16 Q. Okay. Tell me how to say it. 17 A. The 95 percent confidence interval -- 18 Q. That's right. 19 A. -- does cross 1. 20 Q. So we have the 1.04 with the CI crossing 1; 21 correct? 22 A. Yes. 23 Q. Would you refer to the 1.04 as an association 24 that is attenuated but not eliminated? 25 A. Well, first of all, I would not refer to it</p>

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<p>1 as attenuated because that implies that there's a 2 comparison with something else; and in the other 3 paper, it was comparing the full study population to a 4 subset. So I would never refer to this as attenuated. 5 This is what was shown in this particular 6 study. It's an odds ratio of 1.04. It's very close 7 to 1. 8 Q. Fair enough. And fair point about 9 attenuated. 10 Would you refer to a 1.04 with a CI that 11 crosses 1 as a positive association, as professional 12 epidemiologist? 13 A. When I would look at that, I would say that 14 there's little evidence of an association, very close 15 to 1, in this study population -- in this study. 16 Q. You've also published another study coming 17 out of the North Carolina Ovarian Cancer Study; 18 correct? 19 A. I have published quite a few papers that came 20 out of the North Carolina Ovarian Cancer Study. 21 Q. And do you recall publishing a paper in 2010 22 entitled "Primary peritoneal and ovarian cancers: An 23 epidemiologic comparative analysis"? 24 A. I was a coauthor on that paper, yes. 25 Q. Okay. And is this paper discussed in your</p>	<p>1 A. Yes, that's what's reported there based on a 2 quite small sample size. 3 Q. And, again, both of these associations are 4 not statistically significant; correct? 5 A. That is correct. 6 Q. And also I see over here to the left, the 7 category listed here is labeled "Talc use"; correct? 8 A. Yes. 9 Q. So this paper looks specifically at talcum 10 powders; is that right? 11 A. I -- I believe that, in that questionnaire, 12 it was specifically asking about talc use. 13 Q. And, again, the results of this study are not 14 reported in your report; correct? 15 A. As I said before when you asked that, the 16 data from the North Carolina Ovarian Cancer are 17 included in the Terry paper that combined data from 18 multiple studies. 19 Q. On page 11 of your report, Dr. Moorman, you 20 state, in the -- I guess it's the second paragraph 21 down from the top, starting with the "it is important" 22 language. 23 A. Mm-hmm. 24 Q. Okay. And if you look down to the second 25 sentence, you note there that (as read):</p>
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<p>1 expert report at all? 2 A. I don't think that I specifically addressed 3 it. Again, the data from the North Carolina Ovarian 4 Cancer Study was included in the Terry analysis -- 5 MR. JAMES: And I've marked the study 6 that I just referenced as Exhibit No. 17. I'm going 7 to hand you two copies. 8 (Exhibit No. 17 was marked for identification.) 9 BY MR. JAMES: 10 Q. And, Dr. Moorman, if we turn to page 995, 11 there is a Table 2 continued onto page. And if you 12 look down, this paper does report odds ratios for talc 13 use; correct? 14 A. Yes, it does. 15 Q. And for -- if you look over to the right, all 16 the way to the right, you see that you've reported a 17 1.15 not statistically significant association for 18 serous invasive ovarian cancer; correct? 19 A. That's correct. 20 Q. And that's with a CI that crosses 1; correct? 21 A. That is correct. 22 Q. And if you look to the left of that, you've 23 reported here a .76 odds ratio for the relationship 24 between talc use and primary peritoneal cancer; 25 correct?</p>	<p>1 "It is not unusual for scientists 2 and epidemiologists to weigh the 3 Hill factors differently in 4 reaching the conclusion." 5 Correct? 6 A. Yes, I state that. 7 Q. And then in the next sentence, you go on to 8 provide examples of that; correct? 9 A. Correct. 10 Q. And you note there (as read): 11 "The evidence that cigarette 12 smoking causes lung cancer or 13 asbestos causes lung disease." 14 Right? 15 A. Yes. 16 Q. And those are the examples that you're 17 providing to support the prior sentence that 18 epidemiologists can sometimes weigh things 19 differently; is that right? 20 A. I give that as an example, yes. 21 Q. For the two examples that you've provided 22 there, has the medical and scientific community 23 accepted that smoking causes lung cancer and that 24 asbestos causes lung disease? 25 A. I think that, yes, that is true. Now, the</p>

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<p style="text-align: right;">Page 142</p> <p>1 point that I am making here is that some scientists, 2 especially in the early years when the data were 3 accumulating related to smoking and lung cancer, some 4 people weighted the evidence differently. 5 For example, some of the studies looked at 6 whether people reported whether or not they inhaled or 7 not, and some funny results were observed there. And 8 some scientists thought that was really important 9 evidence against an association, whereas others 10 thought it was -- it was not to be regarded very 11 seriously. 12 Q. Do you regard the body of evidence on smoking 13 and asbestos to be equivalent to the body of evidence 14 on talc and ovarian cancer with regard to evaluating 15 cause? 16 MS. PARFITT: Objection. 17 THE WITNESS: Could you clarify what 18 you mean by "equivalent"? 19 BY MR. JAMES: 20 Q. Sure. By providing these two examples 21 here -- first, the smoking example, and second, the 22 asbestos example -- are you suggesting that the body 23 of evidence to support the causal conclusion with 24 respect to asbestos and smoking is qualitatively 25 and/or quantitatively the same or similar to the body</p>	<p style="text-align: right;">Page 144</p> <p>1 that the criteria that I applied to come to a 2 conclusion of causality are based on strong data. 3 MR. JAMES: Object to the nonresponsive 4 answer. 5 THE WITNESS: Maybe you can clarify 6 your question, because I'm -- maybe I didn't 7 understand what you were asking. 8 BY MR. JAMES: 9 Q. Sure. Dr. Moorman, you provided these 10 examples in your report; correct? 11 A. These are examples to make the point that, as 12 we have said here, that some people weigh different 13 parts of the evidence a bit differently. 14 Q. And so if someone who's reading your report 15 gets an impression that you are equating the body of 16 scientific and medical evidence on the issue of 17 smoking and lung cancer to the body of scientific 18 evidence on talc and ovarian cancer, then they would 19 be getting the wrong impression; is that correct? 20 MS. PARFITT: Objection. 21 THE WITNESS: I don't think that I am 22 equating the evidence for the two. I am -- equating 23 the evidence for the two types of cancer. I was using 24 that to illustrate -- to support the sentence right 25 before that, is that, when we look at these Hill</p>
<p style="text-align: right;">Page 143</p> <p>1 of evidence we have in 2019 as to talc and ovarian 2 cancer? 3 A. To say that it is the same is -- I don't know 4 that you can say that it's the same. It's different 5 studies done in different time frames. The assessment 6 of the exposure is a bit different. 7 So there are similarities and, you know, the 8 criteria that I applied to come to my conclusion of 9 causality, I think, are similar to what has been 10 applied to smoking and lung cancer. But the data are 11 different. There are different studies, different 12 time frame. 13 Q. Would you say that the data on smoking and 14 lung cancer is stronger than the data on talc and 15 ovarian cancer -- 16 MS. PARFITT: Objection. 17 BY MR. JAMES: 18 Q. -- to support a causal conclusion? 19 A. I'm not sure why one would make such a 20 comparison of what is stronger or not. I mean, 21 clearly, we know that smoking and lung cancer is one 22 of the strongest associations between an exposure and 23 a cancer. 24 The odds ratio that is associated with talc 25 use and ovarian cancer is not as large, but I think</p>	<p style="text-align: right;">Page 145</p> <p>1 factors, scientists can look at them and they might 2 weight one more heavily than another. 3 BY MR. JAMES: 4 Q. And you -- you believe that the medical 5 community accepts that smoking is a cause of lung 6 cancer; correct? 7 A. Yes, in general, I think that's true. 8 Q. Does the medical community believe that talc 9 is a cause of ovarian cancer? Is that the medical 10 community's consensus? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: I'm not sure who you mean 13 by "the medical community." I -- I think that there 14 are certainly -- there's plenty of evidence to support 15 my conclusion. We have evidence very recently from 16 Health Canada that they have come to the same 17 conclusion. So... 18 BY MR. JAMES: 19 Q. Did Health Canada come to a causal 20 conclusion? 21 A. That was my reading of their document. 22 Q. When's the last time you've read the 23 documents from Health Canada? 24 A. Probably within the last few days. 25 Q. Did Plaintiffs' counsel provide those to you?</p>

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<p>1 A. Yes, they did.</p> <p>2 Q. Okay. And your recollection is that the</p> <p>3 Health Canada documents state that talc is a cause of</p> <p>4 ovarian cancer?</p> <p>5 A. I definitely recall them using the "causal"</p> <p>6 language in the document. If -- we can pull it up if</p> <p>7 we want to confirm the precise language.</p> <p>8 Q. Other than identifying Health Canada, which</p> <p>9 you've just done, are there any other bodies or</p> <p>10 scientific organizations or medical organizations that</p> <p>11 you can cite to that have concluded that talc is a</p> <p>12 cause of ovarian cancer?</p> <p>13 A. We've already discussed the IARC conclusion</p> <p>14 that it's possibly carcinogenic.</p> <p>15 Q. And so, again, I'm asking you about -- sorry.</p> <p>16 A. Sorry. Go ahead.</p> <p>17 Q. Sorry. My apologies.</p> <p>18 A. Okay.</p> <p>19 Q. Were you done?</p> <p>20 A. I'm finished.</p> <p>21 Q. So my question, I think, is different than</p> <p>22 that the one you're answering.</p> <p>23 A. Yeah.</p> <p>24 Q. So I'm asking you if you're aware of any</p> <p>25 scientific or medical bodies that have concluded that</p>	<p>1 ovarian cancer. So...</p> <p>2 Q. And when you say talc -- sorry. I think</p> <p>3 you're dropping off a bit, and so I'm jumping in too</p> <p>4 quickly. And I apologize.</p> <p>5 Are you done?</p> <p>6 A. I'm finished, yes.</p> <p>7 Q. You're referring there to a journal article;</p> <p>8 is that right?</p> <p>9 A. It was a summary of -- I think it was</p> <p>10 something like "What's new in ovarian cancer." It was</p> <p>11 published maybe --</p> <p>12 Q. And do you believe the article that you're</p> <p>13 referring to represents the consensus view of the</p> <p>14 medical community?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: I don't know that it does</p> <p>17 or not. It wasn't presented as the official opinion</p> <p>18 of that organization.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. And the article that you were mentioning, you</p> <p>21 said increased risk -- or increased association. Is</p> <p>22 that what you said? I don't have the realtime in</p> <p>23 front of me right now.</p> <p>24 A. I don't have it in front of me either.</p> <p>25 Q. Okay.</p>
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<p>1 talc is a general cause of ovarian cancer.</p> <p>2 A. I'm not aware of a -- I'm not aware of a</p> <p>3 statement that has been published, other than the ones</p> <p>4 that I mentioned.</p> <p>5 Q. And by others that you mentioned, you're</p> <p>6 referring to the Health Canada document?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And we will turn back to that, and</p> <p>9 that way we can have a copy in front of us both.</p> <p>10 Okay?</p> <p>11 A. Okay.</p> <p>12 Q. With regard to IARC, again, you understand</p> <p>13 that they have concluded "possible." Correct?</p> <p>14 A. They conclude possible at that point in time,</p> <p>15 which was 2010.</p> <p>16 Q. Have you ever looked to see if any medical</p> <p>17 organizations that represent the gynecologic oncology</p> <p>18 community have concluded that talc is a cause of</p> <p>19 ovarian cancer?</p> <p>20 A. I am aware that, in a recent article in</p> <p>21 Obstetrics and Gynecology, which is one of the leading</p> <p>22 journals in the field, they were summarizing some of</p> <p>23 the information that is new. They were describing the</p> <p>24 Penninkilampi meta-analysis, and their conclusion was</p> <p>25 that talc is associated with increased risk for</p>	<p>1 A. I am recalling something like there is --</p> <p>2 I don't know what the phrasing was. It's associated</p> <p>3 with increased risk or there is an increased risk of</p> <p>4 ovarian cancer with talc use.</p> <p>5 Q. Do you recall if that article made a</p> <p>6 statement on causality?</p> <p>7 A. I don't recall.</p> <p>8 Q. Have you consulted information provided by</p> <p>9 the ACOG or the SGO with respect to the talc ovarian</p> <p>10 cancer hypothesis?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: I don't recall if I have</p> <p>13 or not.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. Would you be interested to know the positions</p> <p>16 by the leading organizations for the gynecologic</p> <p>17 oncology community on this issue?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: Of course. Any</p> <p>20 information is important to know.</p> <p>21 MR. JAMES: I'm going to mark as</p> <p>22 Exhibit No. 18 a copy of a statement issued by ACOG on</p> <p>23 talc use and ovarian cancer.</p> <p>24 (Exhibit No. 18 was marked for identification.)</p> <p>25 MR. JAMES: I'm handing you two copies</p>

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<p>1 again.</p> <p>2 BY MR. JAMES:</p> <p>3 Q. Dr. Moorman, have you seen this statement</p> <p>4 before?</p> <p>5 A. I don't recall if I have or not. I might</p> <p>6 have.</p> <p>7 Q. Do you see at the bottom of the statement --</p> <p>8 it's a single paragraph -- the statement concludes</p> <p>9 with the quote (as read):</p> <p>10 "There was no medical consensus</p> <p>11 that talcum powder causes ovarian</p> <p>12 cancer."</p> <p>13 Do you see where I was reading?</p> <p>14 A. I do see that.</p> <p>15 Q. Do you disagree with that statement?</p> <p>16 A. Again, going back to the recent conclusion</p> <p>17 from Health Canada, I think that that is some evidence</p> <p>18 of medical consensus. And I do acknowledge that</p> <p>19 this -- what is said here, that -- yeah, I acknowledge</p> <p>20 what they have written here, yes.</p> <p>21 Q. Have you, in preparing your report for this</p> <p>22 litigation, have you taken a look to see what the</p> <p>23 National Cancer Institute has said about the purported</p> <p>24 association between talc and ovarian cancer?</p> <p>25 A. Yes, I have.</p>	<p>1 inadequate evidence of an association?</p> <p>2 A. Yes.</p> <p>3 And if I may address this document --</p> <p>4 Q. If you could give me just one second, and</p> <p>5 then --</p> <p>6 A. Okay.</p> <p>7 Q. -- I'll let you finish, if you don't mind.</p> <p>8 A. Okay.</p> <p>9 Q. Have you considered this before?</p> <p>10 A. Have I --</p> <p>11 MS. PARFITT: Objection.</p> <p>12 BY MR. JAMES:</p> <p>13 Q. Yes.</p> <p>14 A. -- considered it?</p> <p>15 Q. In forming your opinions in this case?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. It's not cited or discussed in your</p> <p>18 report, is it?</p> <p>19 A. I don't know that I have, but again, it's one</p> <p>20 of the documents that I have -- I have seen in my --</p> <p>21 in my work.</p> <p>22 Q. And so within your report, you do discuss</p> <p>23 findings of IARC; correct?</p> <p>24 A. Yes.</p> <p>25 Q. But you don't discuss findings of the NCI; is</p>
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<p>1 Q. Okay. And what do they say?</p> <p>2 A. I -- when you are -- I think you are</p> <p>3 referring to the PDQ --</p> <p>4 Q. Yes.</p> <p>5 A. -- from NCI.</p> <p>6 Q. Would you like a copy of it?</p> <p>7 A. I would very much like a copy.</p> <p>8 Q. Fair enough.</p> <p>9 Okay. Dr. Moorman, I'm going to hand you a</p> <p>10 copy of the NCI PDQ on "Ovarian, Fallopian Tube, and</p> <p>11 Primary Peritoneal Cancer, Health Professional</p> <p>12 Version."</p> <p>13 (Exhibit No. 19 was marked for identification.)</p> <p>14 THE WITNESS: Thank you.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. And if you turn to -- this is not paginated,</p> <p>17 unfortunately -- have you gotten there already? Or</p> <p>18 I can count for us. I flipped seven times to get</p> <p>19 there. Looks like you beat me to it.</p> <p>20 A. Okay.</p> <p>21 Q. And do you see here that is this the PDQ you</p> <p>22 were thinking of, Dr. Moorman?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And in here, do you see that the NCI</p> <p>25 has listed perineal talc exposure as a factor with</p>	<p>1 that right?</p> <p>2 A. I don't think that I specifically addressed</p> <p>3 it.</p> <p>4 Q. Is that because it conflicts with your</p> <p>5 litigation opinion?</p> <p>6 MS. PARFITT: Objection.</p> <p>7 THE WITNESS: No.</p> <p>8 May I ask --</p> <p>9 BY MR. JAMES:</p> <p>10 Q. And, Dr. Moorman, you said you wanted to</p> <p>11 comment, and now is fine.</p> <p>12 A. Let's see. I wanted -- when did you print</p> <p>13 out this version of the PDQ, if I may ask you?</p> <p>14 Q. So do you understand that this is a -- this</p> <p>15 is a -- well, if you turn to the back page of the copy</p> <p>16 that I handed you --</p> <p>17 A. Mm-hmm.</p> <p>18 Q. -- the very back --</p> <p>19 A. Okay.</p> <p>20 Q. -- it says "Updated: December 21, 2018."</p> <p>21 A. Okay.</p> <p>22 Q. All the way on the back page.</p> <p>23 A. Yeah.</p> <p>24 Q. Got it.</p> <p>25 A. Okay. One of the -- I have looked at this</p>

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<p>1 very recently, and on the online version, there were 2 some rather what I considered kind of interesting 3 conclusions that were made. I'm actually not seeing 4 it in this version here. But, for example, they -- 5 I'm sorry. I don't see it even mentioned here. 6 But on the online version, they had listed 7 DMPA -- depot medroxyprogesterone acetate -- as 8 something that there was adequate evidence of reduced 9 effect. And they were basing that -- there are very 10 few studies on that to begin with, and as they 11 summarized it, again, the last time I looked at it 12 online, they said it was inconsistent data, but they 13 still summarized that there was adequate evidence. 14 And then in regard to things like comparing 15 the evidence for something like breastfeeding, they 16 said (as read): 17 "Based on solid evidence, 18 breastfeeding is associated with 19 decreased risk of ovarian cancer." 20 If we compare the evidence to breastfeeding 21 to the evidence for talcum -- talc use, again, the 22 online version that I last looked at, it gave a little 23 bit more detail about the meta-analyses and so on. 24 So the meta-analyses for breastfeeding and 25 the meta-analyses for talc, there were a lot of</p>	<p>1 with the NCI? 2 A. Okay. Just looking at this, and it came 3 up -- it says "with inadequate evidence of an 4 association." 5 Did you say "adequate" or "inadequate"? 6 Q. I said "inadequate." 7 A. Okay. My judgment based on the evidence is 8 that there is adequate evidence. So I would disagree 9 with the NCI in the conclusion that they reached. 10 Q. With regard to your discussion that we've had 11 just now on the body of evidence to look at 12 breastfeeding and ovarian cancer risk -- 13 A. Yes. 14 Q. -- and this is a yes-or-no question -- did 15 you conduct a comprehensive review of the scientific 16 medical literature and evidence surrounding the 17 association between breastfeeding and ovarian cancer? 18 A. I did not do as comprehensive a review of 19 that literature as I did for the talc. 20 Q. And have you, in the course of your career, 21 ever looked comprehensively at the body of scientific 22 and medical evidence surrounding the association of 23 breastfeeding and ovarian cancer to the cell studies, 24 the plausibility, the dose-response, have you done all 25 of that with respect to breastfeeding and ovarian</p>
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<p>1 similarities. There are roughly 30 studies addressing 2 each of them. For breastfeeding, it's about a 3 25 percent reduction in risk; for talc, about a 4 25 percent increased risk. 5 When you look at the overall number of 6 studies, roughly 90 percent of them support 7 breastfeeding -- in terms of just looking at the 8 direction of the effect -- about 90 percent of them 9 support that breastfeeding is associated with reduced 10 risk. When you look at the meta-analyses for talc, 11 about 90 percent of the studies have an odds ratio 12 greater than 1. 13 And so when we look at the overall body of 14 evidence, to me, I think it's comparable for 15 breastfeeding versus talc, but they conclude that the 16 evidence is adequate for breastfeeding but not 17 adequate for talc. And they don't really describe 18 their methodology for how they reach their 19 conclusions. 20 So it leaves me just a little bit baffled 21 about why is one adequate evidence and one inadequate 22 evidence. 23 Q. If the NCI's PDQ that's available on their 24 website as of today classifies talc as a factor with 25 inadequate evidence of an association, do you disagree</p>	<p>1 cancer? 2 A. I -- in the course of looking at ovarian 3 cancer, I have actually never written a paper that was 4 strictly focused on breastfeeding and ovarian cancer, 5 and that is typically where one would go through the 6 very comprehensive review. 7 I am familiar with much of the literature, 8 but the degree to which I reviewed the literature was 9 not in the same level of detail as I did the talc 10 literature. 11 Q. And do you know if the scientists at the NCI 12 who have commented on the association between 13 breastfeeding and ovarian cancer have conducted an 14 examination of the scientific and medical literature 15 that is more comprehensive, less comprehensive, or the 16 same that you've conducted? 17 MS. PARFITT: Objection to form. 18 THE WITNESS: They do not describe 19 their methodology, and so I can't say if it was more 20 or less comprehensive. 21 BY MR. JAMES: 22 Q. Okay. Dr. Moorman, on page 10 of your 23 report -- 24 A. Yes. 25 Q. -- you have the -- it's the third full</p>

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<p style="text-align: right;">Page 158</p> <p>1 paragraph down, and you make the statement that</p> <p>2 meta-analyses are "considered to be some of the</p> <p>3 strongest evidence for a causal association."</p> <p>4 Do you see where I'm reading that?</p> <p>5 A. Yes, I do.</p> <p>6 Q. Okay. So that's -- so you've made that</p> <p>7 comment.</p> <p>8 And then further down, you say (as read):</p> <p>9 "Data from meta-analyses are</p> <p>10 particularly important for</p> <p>11 evaluating exposure-disease</p> <p>12 relationships such as talc and</p> <p>13 ovarian cancer where the relative</p> <p>14 risks for most individuals are</p> <p>15 approximately 1.2 to 1.5."</p> <p>16 Do you see where I've read that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Can you cite any published authority for the</p> <p>19 statement that meta-analyses are considered to be some</p> <p>20 of the strongest evidence for causal association?</p> <p>21 A. I'm trying to think of whether it's a</p> <p>22 published source. It's something that I have seen,</p> <p>23 for example, multiple times in lectures and so on</p> <p>24 where it will give a hierarchy of evidence. And</p> <p>25 meta-analyses combining data from multiple studies is</p>	<p style="text-align: right;">Page 160</p> <p>1 data as reported. It could not correct the bias.</p> <p>2 Q. So to the extent the meta-analyses are</p> <p>3 collecting data from underlying studies that are</p> <p>4 flawed by recall bias or confounding, those</p> <p>5 inaccuracies carry over into the meta-analyses;</p> <p>6 correct?</p> <p>7 MS. PARFITT: Objection.</p> <p>8 THE WITNESS: I would not characterize</p> <p>9 it as "carry over." We recognize when we combine the</p> <p>10 data from the meta-analyses, it is combining the</p> <p>11 reported data. If there were biases that either led</p> <p>12 to an underestimate or an overestimate of the relative</p> <p>13 risk, they are not correcting that.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. And do you caution the reader of your MDL</p> <p>16 report about that limitation to meta-analyses anywhere</p> <p>17 in your report?</p> <p>18 A. I do not specifically make that caution, no.</p> <p>19 Q. The meta-analyses that we have on the talc</p> <p>20 ovarian cancer issue, they are progressed over a</p> <p>21 period of time; correct?</p> <p>22 A. That is correct.</p> <p>23 Q. And we know that there's been two recent</p> <p>24 meta-analyses. And all of the meta-analyses that have</p> <p>25 been published on this association are in some ways</p>
<p style="text-align: right;">Page 159</p> <p>1 often put at kind of the top of the pyramid for making</p> <p>2 causal assessments.</p> <p>3 I want to say that maybe some of the</p> <p>4 evidence-based medicine -- I know that there are</p> <p>5 online summaries of evidence-based medicine that would</p> <p>6 describe meta-analyses as kind of some of the</p> <p>7 strongest evidence for causality.</p> <p>8 Q. Meta-analyses combine data from underlying</p> <p>9 studies; correct?</p> <p>10 A. That is correct.</p> <p>11 Q. Meta-analyses do not correct for bias and</p> <p>12 confounding in underlying studies; correct?</p> <p>13 A. The meta-analysis itself -- no. They combine</p> <p>14 the data. They...</p> <p>15 Q. And -- were you finished?</p> <p>16 A. Yeah. They do not correct for the bias.</p> <p>17 Q. Meta-analyses, for example, do not eliminate</p> <p>18 recall bias if there is a recall bias problem in the</p> <p>19 underlying studies; correct?</p> <p>20 A. That is correct. Meta-analyses cannot do</p> <p>21 that.</p> <p>22 Q. And the meta-analyses studies that you</p> <p>23 reviewed and discussed in your report all concede that</p> <p>24 point, don't they?</p> <p>25 A. They acknowledge that they are combining the</p>	<p style="text-align: right;">Page 161</p> <p>1 overlapping; correct?</p> <p>2 MS. PARFITT: Objection to form.</p> <p>3 THE WITNESS: The meta-analyses, their</p> <p>4 intent is to combine all the published data. So, yes,</p> <p>5 there is some overlap. More recent ones would have</p> <p>6 included studies that had been published in prior</p> <p>7 meta-analyses.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. And recognizing that meta-analyses can differ</p> <p>10 here and there for various -- various reasons, the</p> <p>11 talc ovarian cancer meta-analyses generally pull data</p> <p>12 from the same body of literature; is that fair?</p> <p>13 A. Yes.</p> <p>14 Q. And any suggestion that because you have</p> <p>15 multiple meta-analyses reaching around the same odds</p> <p>16 ratio and that that somehow demonstrates consistency,</p> <p>17 isn't that a little bit misleading?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: I think that when we look</p> <p>20 at it, when we see that, early on, you see some</p> <p>21 meta-analyses were done, I want to say maybe in the</p> <p>22 '90s, and then as more data are added in, you -- they</p> <p>23 still settled in on roughly the same summary odds</p> <p>24 ratio as even more data were accumulated.</p> <p>25 Sometimes there is a concern that early on</p>

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<p>1 the studies with positive associations are published, 2 and then after -- as time goes on, other studies are 3 done that didn't find that association. So you would 4 expect that the summary odds ratio might become 5 attenuated as more studies were added. 6 And that's not the situation with the talc 7 literature. It's been pretty consistent from the 8 meta-analyses done in the 1990s to the 2000s to 2018. 9 BY MR. JAMES: 10 Q. And the 2018 meta-analyses that they are 11 grabbing in the studies from decades prior, they're 12 grabbing in the same studies that the 1990s 13 meta-analyses grabbed in; right? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: Yeah. The purpose is to 16 include all of the published data. So yes, of course. 17 BY MR. JAMES: 18 Q. And in your report, you place significant 19 emphasis -- if that's a fair word -- on meta-analyses. 20 Is that a fair way to describe it? 21 MS. PARFITT: Objection. 22 THE WITNESS: Yes, I think I -- I think 23 that's fair to characterize it that way. 24 BY MR. JAMES: 25 Q. You -- did you read the conclusions of all of</p>	<p>1 opportunity to ask questions afterwards. 2 A. Some of them did raise some concerns about 3 whether or not it could be a causal association. 4 Q. We're going to take a look at the studies 5 shortly as I grab these folders out. 6 Did you report in your report for the MDL 7 any of the cautionary language from these 8 meta-analyses about causation? 9 A. I -- in my report, when you look at some of 10 the cautionary language, they will refer to perhaps 11 concerns about recall bias or things like that. 12 In my report, I went through potential 13 biases and how I weighed that and whether I thought it 14 was an important concern in the studies that 15 contributed to the meta-analyses. 16 Q. Did you talk about any weaknesses or problems 17 with the meta-analyses themselves? 18 A. I don't believe I did in my report. 19 Q. And just -- okay. 20 MR. JAMES: I'm going to mark as 21 Exhibit No. 20 a meta-analysis that I think that 22 you've mentioned this morning. It's the Penninkilampi 23 study. 24 THE WITNESS: Yes. 25 MR. JAMES: I'm going to hand you two</p>
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<p>1 the meta-analyses performed to date? 2 A. I did. 3 Q. Do any of the authors of the meta-analyses 4 performed to date conclude causation? 5 A. If I may take a minute to address the issue 6 of how causation is reported in the epidemiologic 7 literature. 8 Q. With all due respect, Doctor, if you could 9 just answer the question. 10 A. I think that they typically refer to, like, 11 increased risk. I don't know that any of them refer 12 to -- made the conclusion of -- I don't know that they 13 used the word "causal." 14 Q. In fact, many of the meta-analyses 15 specifically caution against a causal interpretation, 16 don't they? 17 MS. PARFITT: Objection. 18 THE WITNESS: Once again, if -- may 19 I take a moment to address how the word -- 20 BY MR. JAMES: 21 Q. Because my time is limited -- 22 A. Okay. 23 Q. -- I'm really going to have to respectfully 24 ask you to answer my question to the extent that 25 you're able, and then your counsel will have an</p>	<p>1 copies again. 2 (Exhibit No. 20 was marked for identification.) 3 MR. JAMES: It's marked as Exhibit 20. 4 THE WITNESS: Would this be a good time 5 to take a break before we get into -- 6 MR. JAMES: Absolutely. 7 THE WITNESS: Okay. 8 THE VIDEOGRAPHER: Going off record at 9 1:48 p.m. 10 (Recess taken from 1:48 p.m. to 2:03 p.m.) 11 THE VIDEOGRAPHER: Back on record at 12 2:03 p.m. 13 BY MR. JAMES: 14 Q. Dr. Moorman, I handed you had a copy of the 15 Penninkilampi paper. 16 A. I'm sorry, the papers were moved while 17 I was... 18 Q. It was marked as Exhibit 20, I believe. 19 Here, I have an extra, if that would speed 20 things along. I'm sure it's somewhere in there. 21 A. It got moved around. Oh, here it is. 22 Q. Okay. Again, Dr. Moorman, this is one of the 23 meta-analyses that you reviewed to inform your 24 opinions in this case; correct? 25 A. That is correct.</p>

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<p style="text-align: right;">Page 166</p> <p>1 Q. It's also one of the more recent 2 meta-analyses on the issue; correct? 3 A. That's correct. 4 Q. And what did the Penninkilampi authors say 5 about causation? 6 A. Okay. They describe perineal talc is 7 associated with a 24 to 39 percent increased risk of 8 ovarian cancer. 9 And this is a very typical way that it would 10 be described in the epidemiologic literature. It -- 11 as described very eloquently in some articles in the 12 American Journal of Public Health last spring, they 13 noted that, to the detriment of the science, that 14 epidemiologists are frequently loathe -- or don't 15 often use the word "causal" when they describe a risk 16 factor; and, in part, this is because we are relying 17 on observational data. This is not an experimental 18 study. 19 And so, many times, reviewers, if they refer 20 to "we found that talc caused ovarian cancer," they 21 would object to that, saying that it wasn't a 22 randomized controlled trial. 23 But in this series of articles in the 24 American Journal of Public Health, they indicated that 25 the tendency not to use the word "causal" is to the</p>	<p style="text-align: right;">Page 168</p> <p>1 "Hence, while perineal talc use 2 has not been shown to be safe, in 3 a similar regard, a certain causal 4 link between talc use and ovarian 5 cancer has not yet been 6 established." 7 That's what the authors say; correct? 8 A. That's what they say, yes. 9 Q. Okay. So they caution that causation has not 10 been established; correct? 11 MS. PARFITT: Objection. 12 THE WITNESS: They say a certain causal 13 link has not been established -- not yet been 14 established. 15 BY MR. JAMES: 16 Q. And you're here today testifying about what 17 you believe to be evidence supporting the causal link; 18 correct? 19 A. Yes, I am -- I am. 20 Q. Okay. And so where in your report do you 21 advise the reader that the Penninkilampi authors 22 expressed reservations about causation? 23 A. I do not have anything like that in my 24 report. 25 MR. JAMES: The next meta-analysis that</p>
<p style="text-align: right;">Page 167</p> <p>1 detriment of the science. It's like "Why would we be 2 looking at risk factors for a disease if we didn't 3 think that it caused the disease?" 4 So I think that when an epidemiologist sees 5 an increased risk of ovarian cancer, we are thinking 6 that this is -- this causes ovarian cancer. 7 Q. But epidemiologists, including many of the 8 meta-analyses that we're about to review, have talked 9 about cause, haven't they? 10 MS. PARFITT: Objection. 11 THE WITNESS: Some of them have 12 addressed, yes. 13 BY MR. JAMES: 14 Q. For example, Penninkilampi doesn't seem shy 15 of the word "cause." If we look at page 42, 16 Dr. Moorman, we see, in the top paragraph in the 17 left-hand column, at the bottom of that paragraph, the 18 Penninkilampi authors write, quote -- this is the last 19 sentence -- 20 A. Wait. Page 42? 21 Q. Page 42. 22 A. Yes. 23 Q. It's the top left paragraph. The bottom last 24 sentence of that paragraph, the authors state 25 (as read):</p>	<p style="text-align: right;">Page 169</p> <p>1 we can look at is the Berg -- or Berge meta-analysis. 2 I'm going to mark that as Exhibit 21. 3 (Exhibit No. 21 was marked for identification.) 4 BY MR. JAMES: 5 Q. Do the Berge authors conclude that the 6 evidence is sufficient to support a causation 7 conclusion? 8 A. They do not make that conclusion, no. 9 Q. In fact, they actually -- they do address 10 causation, don't they? 11 A. They state their opinion, yes. 12 Q. Okay. And their opinion is expressed several 13 times throughout the article. The first is in the 14 abstract of the article; correct? 15 If we look at the abstract, it's the first 16 page of the article, page 248, the last sentence of 17 the abstract. Do you see that? 18 A. Yes, I do. 19 Q. They say (as read): 20 "The heterogeneity of results by 21 study design, however, detracts 22 from a causal interpretation of 23 this association." 24 Correct? 25 A. That's what it says, yes.</p>

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<p style="text-align: right;">Page 170</p> <p>1 Q. Where do you advise the reader of your MDL 2 report that the authors of the Berge meta-analyses 3 expressed reservations about causation? 4 MS. PARFITT: Objection. Form. 5 THE WITNESS: That is not in my report. 6 BY MR. JAMES: 7 Q. Do you see at the very the end of article, at 8 the very last page on 256, before the acknowledgment 9 section, again, the authors conclude the article with 10 a statement that the results (as read): 11 "do not support a causal 12 interpretation of the 13 association." 14 Do you see where I'm reading? 15 A. They say some -- several aspects of the 16 results there. 17 Q. Fair enough. 18 A. Yes. 19 Q. So let's just read the sentence in full. So 20 they say (as read): 21 "Several aspects of our results, 22 including the heterogeneity of 23 results between case-control and 24 cohort studies, however, do not 25 support a causal interpretation of</p>	<p style="text-align: right;">Page 172</p> <p>1 MR. JAMES: And I'm going to reserve 2 the time that it takes -- 3 MS. PARFITT: No, you're not going to 4 reserve the time. You asked her a question; she was 5 answering it. 6 MR. JAMES: It was a yes-or-no 7 question. 8 MS. PARFITT: You can object -- it was 9 not, Scott. Let's have her finish her statement, and 10 you can decide what you want to do it with it. But 11 she's going to finish her comment. 12 Dr. Moorman, please. 13 THE WITNESS: So I think that in my 14 report, I did address the aspects of the heterogeneity 15 of the results, although I might not specifically have 16 addressed -- said anything specifically about the 17 limitation of the Berge. 18 BY MS. PARFITT: 19 Q. Right. So my question, which was very 20 precise, is where do you note in your MDL report the 21 causation reservations of the Berge authors? 22 MS. PARFITT: Objection. 23 THE WITNESS: And as I stated before, 24 that is not in -- that specific reservations of the 25 Berge authors, I do not have that in my -- in my</p>
<p style="text-align: right;">Page 171</p> <p>1 the association." 2 That's what they say; correct? 3 A. Right. 4 Q. And, again, do you advise the readers of your 5 MDL report that those are the conclusions of the Berge 6 meta-analysis? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: I do not specifically do 9 that. But in my report, I think that I really address 10 some of the heterogeneity of the results between 11 case-control and cohort studies and why some of the 12 differences might be observed and, for example, some 13 of the biases in the cohort studies would lead to an 14 underestimate of the -- 15 BY MR. JAMES: 16 Q. And, Dr. Moorman -- 17 MS. PARFITT: Excuse me -- 18 BY MR. JAMES: 19 Q. -- I'm going to ask you questions about that. 20 MS. PARFITT: -- Mr. James, she was in 21 the middle of her sentence. 22 MR. JAMES: I object to the 23 nonresponsive portion of her answer. 24 MS. PARFITT: You may, but let her 25 complete her answer.</p>	<p style="text-align: right;">Page 173</p> <p>1 report. 2 BY MS. PARFITT: 3 Q. The next meta-analyses is -- and I'm working 4 backwards chronologically -- is the Langseth 5 meta-analyses. 6 Are you familiar with that paper? 7 A. Yes, I have seen that paper. 8 MR. JAMES: And I'm going to mark the 9 Langseth paper as Exhibit No. 23. 10 (Exhibit No. 22 was marked for identification.) 11 MR. JAMES: I'm handing you two copies. 12 MR. DONATH: 23 or 22? 13 MS. BRENNAN: 22. 14 MR. JAMES: It's 22. So we'll sub 15 stickers. 16 BY MR. JAMES: 17 Q. So Langseth is 22. Did the authors of 18 Langseth conclude that causation is shown? Yes or no, 19 please. 20 A. They -- if I may take just a moment to read 21 through it -- 22 Q. Sure. 23 A. -- as it... 24 No, they do not. 25 Q. And, in fact, the authors do address the</p>

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<p style="text-align: right;">Page 174</p> <p>1 issue of causation on page 359 of the article; 2 correct, under the section "Proposal to research 3 community." 4 Do you see where I am? 5 A. I do see that. 6 Q. Okay. And the authors state (as read): 7 "The current body of experimental 8 and epidemiological evidence is 9 insufficient to establish a causal 10 association between perineal use 11 of talc and ovarian cancer risk." 12 A. That is correct. And, again, noting the date 13 of this paper, 2008. So quite a lot of evidence has 14 emerged since then. And one of the authors on the 15 paper has since concluded that there is sufficient 16 evidence for causality. 17 Q. And you're talking about a paid expert in 18 this case; correct? 19 MS. PARFITT: Objection. 20 THE WITNESS: Dr. Siemiatycki, who's a 21 paid expert, well-respected epidemiologist. 22 BY MR. JAMES: 23 Q. And he's a paid expert in this litigation for 24 the Plaintiffs; correct? 25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 176</p> <p>1 conclude that the evidence was sufficient to support 2 causation? 3 A. No, they did not. 4 Q. Okay. And, in fact, the authors did address 5 causation in their paper in the abstract; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: Yes, they do. 8 BY MR. JAMES: 9 Q. Okay. And at page 195 in the conclusion of 10 the abstract, the authors say (as read): 11 "The available observational data 12 do not support the existence of a 13 causal relationship between 14 perineal talc exposure and 15 increased risk of epithelial 16 ovarian cancer. Selection bias 17 and uncontrolled confounding may 18 account for the positive 19 associations seen in prior 20 epidemiological studies." 21 That's what the authors say; correct? 22 A. That is what these authors say. 23 Q. And did you report to the reader of your MDL 24 report the Huncharek authors' reserved judgment on 25 causation?</p>
<p style="text-align: right;">Page 175</p> <p>1 THE WITNESS: That is correct. 2 BY MR. JAMES: 3 Q. Where in your report -- and this is a 4 yes-or-no question, or actually it's not "yes" or 5 "no." You tell me if it exists or not. 6 Where in your report do you show to the 7 reader of the report that the Langseth authors 8 reserved judgment on causation? 9 MS. PARFITT: Objection to form. 10 THE WITNESS: I did not specifically 11 include that in my report. 12 BY MR. JAMES: 13 Q. Dr. Moorman, have you reviewed the Huncharek 14 2003 meta-analyses? 15 A. Yes, I have. 16 MR. JAMES: And I'm going to mark the 17 Huncharek 2003 meta-analyses as Exhibit No. 23, and 18 we'll switch stickers at the break. 19 (Exhibit No. 23 was marked for identification.) 20 BY MR. JAMES: 21 Q. I'm handing you two copies, Dr. Moorman. 22 Is this another meta-analysis that you 23 reviewed in forming your opinions in this case? 24 A. Yes, it is. 25 Q. Okay. Did the authors of this meta-analysis</p>	<p style="text-align: right;">Page 177</p> <p>1 MS. PARFITT: Objection. 2 THE WITNESS: As with the other 3 meta-analysis, this is now 16 years old, and I did not 4 specifically report that, but I did consider in my 5 report the biases and uncontrolled confounding that 6 they were concerned about. 7 BY MR. JAMES: 8 Q. Do any of the -- there are a handful of 9 meta-analyses that precede the Huncharek 2003 10 meta-analyses; correct? 11 A. That is correct. 12 Q. Do any of those meta-analyses conclude 13 causation? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: I don't believe that they 16 do. 17 BY MR. JAMES: 18 Q. And returning back to our discussion on the 19 Langseth meta-analyses, you noted sort of -- when I 20 asked you a question about their conclusions on 21 causation, you noted the timing of the article; 22 correct? 23 A. Yes. 24 Q. You noted that the article was published 25 in --</p>

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<p>1 A. 2008. 2 Q. -- 2008? 3 A. Yes. 4 Q. That is right? 5 So is your opinion that the evidence in 2008 6 was, in fact, insufficient to support a causal 7 conclusion but has now transitioned to a status where 8 it is sufficient? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: You have asked me that 11 question in -- that or a similar question before. 12 There is a growing body of evidence. 13 I would be hard-pressed to say at what point in time, 14 you know, it reached the tipping point where there is 15 enough evidence to say that there is this causal 16 association. 17 At this point in time, I feel very confident 18 in saying that, but I can't say when sufficient data 19 accumulated to say that. I think that's an impossible 20 answer -- or an impossible question to answer. 21 BY MR. JAMES: 22 Q. And the reason I asked it again is because 23 you made the qualification in discussing the Langseth 24 paper. When I asked you about the authors' 25 conclusions on causation, you specifically noted that</p>	<p>1 A. No -- 2 MS. PARFITT: Objection. 3 THE WITNESS: -- for the same reasons 4 I described prior. 5 MR. JAMES: And I'm going to mark the 6 2013 Terry paper as Exhibit 24. 7 (Exhibit No. 24 was marked for identification.) 8 MR. JAMES: I think I'm back on track 9 on the numbers. I'm handing you two copies. 10 BY MR. JAMES: 11 Q. And again, Dr. Moorman, you've used this 12 paper to inform your opinions in the case; correct? 13 A. That is correct. 14 Q. And if you look at the last page of the text 15 on 820 with me, you see in the last paragraph, which 16 is -- the last paragraph on page 820, the authors 17 state at the top right-hand column (as read): 18 "More work is needed to understand 19 how genital powders may exert a 20 carcinogenic effect and which 21 constituents may be involved." 22 Do you see that sentence? 23 A. Yes, I do. 24 Q. There, the authors are again noting that -- 25 let me rephrase it this way.</p>
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<p>1 it was a paper from the 2008 time frame; correct? 2 A. Right. And I think that -- I think that it 3 is obvious that one of the authors, considering all 4 the additional data that's accumulated, would -- has 5 made a different conclusion at this point in time. 6 Q. And the author you're referring to there is 7 the author that we were discussing as a paid expert in 8 this case; correct? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: Yes. We established he 11 is a paid expert and, at the same time, a very 12 well-respected epidemiologist. 13 BY MR. JAMES: 14 Q. There's also a pooled analysis that you 15 looked at to inform your opinions in this case; 16 correct? 17 A. Yes. 18 Q. Okay. And the pooled analysis is the Terry 19 2013 paper? 20 A. That is correct. 21 Q. Okay. Did the Terry 2013 paper conclude 22 cause? 23 MS. PARFITT: Objection. Form. 24 BY MR. JAMES: 25 Q. It's yes or no.</p>	<p>1 The authors there are reserving judgment on 2 causation; correct? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I don't think that that 5 is how I would necessarily interpret that. 6 BY MR. JAMES: 7 Q. Okay. 8 A. I think that, first of all, basically, any 9 scientific paper concludes with "more work is needed." 10 And so it's talking about, you know, trying to advance 11 scientific knowledge by understanding the biological 12 mechanism. 13 But I don't see anything -- any statement 14 there related to causal. It says "small to moderate 15 increased risk of ovarian cancer." And as I've stated 16 previously, basically, when we talk about risk 17 factors, we are thinking that this is something that 18 causes this cancer. 19 Q. So in your professional opinion, the word 20 "risk factor" is equivalent to "causation"? 21 A. Not always equivalent. And if I may give an 22 example. 23 Women who have higher educational level are 24 at increased risk for breast cancer. And so higher 25 education level, we might describe it as a risk factor</p>

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<p>1 for breast cancer. But, clearly, going to college is</p> <p>2 not going to cause breast cancer. It's the other</p> <p>3 factors that are associated with it, like your</p> <p>4 childbearing patterns, alcohol use, other things.</p> <p>5 But when we talk about a risk factor and</p> <p>6 there is a plausible biological mechanism to get from</p> <p>7 that exposure to cancer, I think that "risk factor"</p> <p>8 and "cause" are pretty synonymous.</p> <p>9 Q. But to say something is associated in</p> <p>10 epidemiologic literature is not to say that it's</p> <p>11 causal.</p> <p>12 Do you agree with that?</p> <p>13 MS. PARFITT: Objection.</p> <p>14 THE WITNESS: Yes. That's kind of</p> <p>15 epi 101, that everything that is associated is not</p> <p>16 necessarily a cause.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. To reach a causal conclusion, it's -- one</p> <p>19 must undertake a more in-depth analysis; correct?</p> <p>20 A. As I did for this, and as all of us in this</p> <p>21 room are well aware, the Bradford Hill framework is a</p> <p>22 framework for taking the data and leading to making a</p> <p>23 judgment on causality.</p> <p>24 Q. So if a paper refers to something as a risk</p> <p>25 factor or a potential risk factor or a modifiable risk</p>	<p>1 meta-analyses.</p> <p>2 Q. Are you aware of any flaws in the</p> <p>3 Penninkilampi study?</p> <p>4 MS. PARFITT: Objection. Form.</p> <p>5 THE WITNESS: Overall, I felt like it</p> <p>6 seemed to be a very well done meta-analysis. When we</p> <p>7 look at judgments of meta-analyses, we like to see</p> <p>8 things like, you know, what were the search terms they</p> <p>9 used? What were the criteria for including or</p> <p>10 excluding studies? Were the study questions defined</p> <p>11 in advance?</p> <p>12 And when I look through all of that,</p> <p>13 I judged it overall to be a very well done</p> <p>14 meta-analysis.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. And so your answer to the question that</p> <p>17 I asked is no; correct?</p> <p>18 MS. PARFITT: Objection.</p> <p>19 THE WITNESS: I -- I don't see any</p> <p>20 serious problems with any -- you characterized it as</p> <p>21 "flaws." I don't -- I don't see anything that I would</p> <p>22 characterize as a flaw in their methodology.</p> <p>23 BY MR. JAMES:</p> <p>24 Q. If you look at page 47 with me, Dr. Moorman,</p> <p>25 in the "Conclusions" section.</p>
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<p>1 factor, that terminology by itself does not suggest</p> <p>2 that the authors of that paper have concluded</p> <p>3 causation; correct?</p> <p>4 A. I -- I think that I have answered that</p> <p>5 question already.</p> <p>6 When they're -- if they refer to it as a</p> <p>7 risk factor, they may or may not have gone through the</p> <p>8 full Bradford Hill evaluation of it. And then, also,</p> <p>9 some things that we refer to as risk factors, where</p> <p>10 there is not a plausible biological mechanism, we</p> <p>11 wouldn't equate risk factor and cause in that</p> <p>12 situation as well.</p> <p>13 Q. So you -- returning back to the Penninkilampi</p> <p>14 meta-analysis, which I believe will be somewhere in</p> <p>15 that pile --</p> <p>16 A. Mm-hmm.</p> <p>17 Q. -- you cite Penninkilampi 14 times in your</p> <p>18 report.</p> <p>19 Were you aware of that?</p> <p>20 A. I don't know how many times I've cited it.</p> <p>21 Q. It's one of the most cited articles in your</p> <p>22 report.</p> <p>23 Were you aware of that?</p> <p>24 A. I know that I referred to it frequently</p> <p>25 because it is one of the most up-to-date, most recent</p>	<p>1 The conclusions section, I think you had</p> <p>2 previously read in the first sentence of the</p> <p>3 conclusions, the percentage increased risk reported in</p> <p>4 the paper.</p> <p>5 The second sentence says (as read):</p> <p>6 "While the results of case-control</p> <p>7 studies are prone to recall bias,</p> <p>8 especially with intense media</p> <p>9 attention following the</p> <p>10 commencement of litigation in</p> <p>11 2014, the confirmation of an</p> <p>12 association in cohort studies</p> <p>13 between perineal talc use and</p> <p>14 serous invasive ovarian cancer is</p> <p>15 suggestive of a causal</p> <p>16 association."</p> <p>17 Do you see where I was reading?</p> <p>18 A. Yes, I do.</p> <p>19 Q. Okay. So here we see that Penninkilampi is</p> <p>20 acknowledging the recall bias problems of the</p> <p>21 case-control studies; correct?</p> <p>22 A. They are acknowledging that it is a</p> <p>23 possibility.</p> <p>24 Q. Okay.</p> <p>25 A. Okay.</p>

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<p>1 MS. PARFITT: Wait. Are you still -- 2 thank you. 3 Please, finish. 4 THE WITNESS: Yes. And, you know, this 5 is, again, one of the things that I addressed in my 6 report. I very carefully considered recall bias and 7 how it could have contributed or not to the elevated 8 risk that has been seen across so many studies. 9 BY MR. JAMES: 10 Q. And one of the -- so within the sentence 11 "after acknowledging the recall bias" that we just 12 discussed, the Penninkilampi authors emphasize the 13 confirmation of an association in cohort studies. 14 Do you see that? 15 A. I do. 16 Q. Okay. Are there cohort studies that support 17 the association? 18 A. There are three cohort studies that have 19 examined talc use and ovarian cancer, and you're 20 probably very much aware of them: the Gonzalez study, 21 the Houghton -- which was from the Sister Study -- the 22 Houghton study, which was the Women's Health 23 Initiative; and the Nurses' Health Study, which has 24 been published in several of them. 25 And as they indicate in here, when you look</p>	<p>1 entirely sure of their rationale for why they looked 2 at one rather than the other. There were some 3 differences between the studies; like the later study, 4 the unexposed group was actually women who had used it 5 for less than once a week rather than never used. And 6 so they don't really go into the detail why they made 7 that decision. 8 But investigators will make a judgment 9 sometimes about which of a -- which studies to include 10 when there's more than one publication from a given 11 study. 12 Q. And do you know that with respect to the NHS 13 cohort, they have published two studies arising from 14 the NHS cohort looking at the issue of talc and the 15 ovarian cancer association; correct? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: They actually -- they 18 have published two studies, and data from the Nurses' 19 Health Study was also included in at least one other 20 publication. I believe Cramer was -- I'm not sure if 21 he was the first author or one of the authors where 22 they combined data. 23 BY MR. JAMES: 24 Q. The NHS cohort has published two papers with 25 respect to the talc/ovarian cancer association;</p>
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<p>1 at the studies that reported on invasive serous -- and 2 if you will give me just a second here -- find it on 3 this paper. Okay. 4 When they report in Table 2 that combining 5 the two studies that reported on the histologic 6 subtypes, there was a significantly increased risk of 7 serous invasive cancer in the cohort studies as well 8 in the case-control studies. 9 Q. Sorry. 10 A. Okay. 11 Q. You did pause there. 12 A. I did. 13 The one study that really found no 14 association whatsoever with talc was the Gonzalez 15 study, the Sister Study, that has numerous problems 16 with it, most specifically in their assessment of the 17 talc exposure, the sample size, the duration of 18 follow-up. 19 Q. And returning to my question about this 20 article, were you aware that the Penninkilampi authors 21 didn't factor in the Gates 2010 data at all? 22 A. When one does a meta-analysis, sometimes when 23 data are reported in a couple of reports, you have to 24 make a decision about which one to include. 25 I believe they used data from the -- I'm not</p>	<p>1 correct? 2 A. I just answered the question. It's -- data 3 from it was also in another -- in another publication. 4 Q. The Gertig 2000 paper reported on the 5 talc/ovarian cancer association; correct? 6 A. Yes. 7 Q. And that's an NHS publication; correct? 8 A. It is. 9 Q. The Gates 2010 paper reported on talc/ovarian 10 cancer association; correct? 11 A. That is correct. 12 Q. And that's an NHS publication; correct? 13 A. Correct. 14 Q. An NHS publication of 2010 offered an 15 additional ten years of follow-up to the talc/ovarian 16 cancer hypothesis; correct? 17 MS. PARFITT: Objection. Form. 18 THE WITNESS: It was additional 19 follow-up, but no update on exposure during that 20 time -- period of follow-up. 21 BY MR. JAMES: 22 Q. For that period of follow-up, they followed 23 the study participants for an additional ten years; 24 correct? 25 MS. PARFITT: Objection. Form.</p>

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<p>1 THE WITNESS: Yes. I answered that 2 already. Yes. 3 BY MR. JAMES: 4 Q. And you agree more follow-up for a cohort is 5 better; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: In general, longer 8 follow-up would be desirable. However, when they're 9 not updating exposure information, that could -- that 10 creates a bias, a possible bias. 11 BY MR. JAMES: 12 Q. Do you think the 2010 data and the Gates 13 paper with respect to the talc ovarian cancer issue is 14 superior to the 2000 data in the Gertig 2000 paper? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: I already made the point 17 that how they define the unexposed group was different 18 between the two studies; and so including some women 19 who had low levels of exposure in their unexposed 20 group, that could potentially have had the effect of 21 attenuating the association. 22 And so, you know, longer follow-up is 23 generally better, but some of the other things they 24 did, that's -- they were not so good. 25</p>	<p>1 Q. So one of your complaints -- 2 A. So I -- 3 Q. Sorry. 4 A. Okay. 5 Q. One of your issues with the cohort studies is 6 lack of follow-up; correct? 7 A. For -- yes, for -- there are -- it's one of 8 several concerns I have about the cohort studies. 9 Q. And the Penninkilampi study did not factor in 10 the additional period of follow-up through the 2010 11 paper; correct? 12 A. I don't believe they did. I think they went 13 with the earlier study. 14 Q. In fact, they didn't even cite to the Gates 15 2010 data, did they? 16 MS. PARFITT: Objection. 17 THE WITNESS: No, they -- they didn't. 18 BY MR. JAMES: 19 Q. And they didn't offer any explanation about 20 why they went with the earlier study, did they? 21 A. Not that I recall. 22 Q. And do you understand that in the 2010 NHS 23 paper through Gates, the association with serous 24 ovarian cancer washed out? 25 MS. PARFITT: Objection to form.</p>
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<p>1 BY MR. JAMES: 2 Q. Elsewhere in your report, you do complain 3 about lack of follow-up in the cohort studies, don't 4 you? 5 A. I do mention that as one of the limitations, 6 yes. 7 Q. And you specifically discuss the NHS cohort 8 as having a period of -- I believe you say it's 9 14 years; is that right? 10 A. From -- yeah. I -- I can't remember 11 specifically. It's from the 1980s to -- I don't 12 remember the exact date of the last -- the last date 13 of follow-up in their papers. 14 Q. And, again, that's the exposure period that 15 Penninkilampi is looking at as well; correct? 16 Or excuse me, not the exposure period, the 17 period of time that they follow the study 18 participants; correct? 19 Penninkilampi is looking at from 20 questionnaire to 2000; correct? 21 A. Correct. 22 Q. Okay. And when you say in your report that 23 the NHS study has a 14-year follow-up period, that's 24 what you're looking at too, as well; correct? 25 A. Right. From the time of exposures --</p>	<p>1 THE WITNESS: "Washed out," I don't 2 like that term. But again, I fully acknowledge that 3 the later study showed weaker associations, yes. 4 BY MR. JAMES: 5 Q. And the association for serous invasive 6 ovarian cancer in the Gates 2010 paper was not 7 statistically significant; correct? 8 A. I believe that is correct. 9 Q. So when you include the critique in your 10 report about the follow-up being a 14-year period, you 11 also, like Penninkilampi, aren't crediting the 12 additional ten years of follow-up that the Gates paper 13 published on; correct? 14 MS. PARFITT: Objection to form. 15 THE WITNESS: "Aren't crediting the 16 additional ten years of follow-up." 17 You know, as I have stated before, when 18 people do meta-analyses, they will make decisions 19 about which studies to include. I acknowledge that 20 Penninkilampi didn't describe in detail why they went 21 with the Gertig rather than a later study. 22 My understanding, however, is that other 23 people -- other meta-analyses have looked at -- have 24 included the later study, and the overall conclusions 25 were not changed in any real way.</p>

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<p>1 BY MR. JAMES: 2 Q. Well, Penninkilampi, you say, didn't describe 3 in detail about why they went with the earlier study, 4 but, in truth, they didn't describe it at all. 5 MS. PARFITT: Objection. 6 THE WITNESS: That's -- that's correct. 7 BY MR. JAMES: 8 Q. And when you refer to other studies that 9 have, in fact, looked at the Gates 2010 cohort data 10 that provides a longer period of follow-up, those 11 papers have necessarily noted that the serous 12 relationship found in Gertig 2000 disappeared in 2010; 13 correct? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: Can you -- can we -- tell 16 me which -- specifically which article you're -- 17 BY MR. JAMES: 18 Q. Sure. Let's turn to the Berge article. 19 A. Okay. 20 Q. The Berge article was marked as 21 Exhibit No. 21. And you have it before you, Doctor? 22 A. I do. 23 Q. Okay. And if you turn to Figure 2, which is 24 on page 254, do you see that there that in the forest 25 plot, they have listed the cohort studies at the</p>	<p>1 BY MR. JAMES: 2 Q. They're heterogeneous. Did I pronounce that 3 correctly? 4 A. No. Heterogeneous. 5 Q. Heterogeneous. Thank you. I figured I got 6 that wrong. 7 So what they're saying there is that the 8 results by the study design are different; right? 9 A. That's -- yes, that's what they are saying. 10 Q. And here we see, again, that this study used 11 the more recent data; correct? 12 MS. PARFITT: Objection. Form. 13 THE WITNESS: It used the more recent 14 publication from the Nurses' Health Study, yes. 15 BY MR. JAMES: 16 Q. Which includes the more recent data; correct? 17 MS. PARFITT: Objection. 18 THE WITNESS: Yes. 19 BY MR. JAMES: 20 Q. On page 8 of your report, Dr. Moorman, you 21 say at the bottom paragraph (as read): 22 "Cohort studies and case-control 23 studies each have advantages and 24 disadvantages for assessing talc 25 as a risk factor for ovarian</p>
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<p>1 bottom; correct? 2 A. Correct. 3 Q. Okay. And there they report data from the 4 Gates 2010 study; correct? 5 A. Correct. 6 Q. Okay. They do not report the data from the 7 Gertig 2000 paper; correct? 8 A. That is correct. 9 Q. And if you look at the conclusions of the 10 Berge authors -- and we talked about this before -- 11 but if you look at the abstract of the paper, 12 Dr. Moorman, the authors say (as read): 13 "The heterogeneity of results by 14 study design, however, detracts 15 from a causal interpretation of 16 this association." 17 Do you see that? 18 A. Yes. You've asked that before. Yes. 19 Q. And what the authors there are saying is that 20 the results from the case-control studies, the 21 meta-analyses of the case-control studies, and the 22 results of the meta-analyses of the cohort studies are 23 different; right? 24 MS. PARFITT: Objection. 25 THE WITNESS: They -- yes.</p>	<p>1 cancer, and one study design is 2 not clearly superior to the 3 other." 4 Do you see where I was reading that? 5 A. Yes, I do. 6 Q. So your expert opinion in this case is that 7 the cohort studies on talc ovarian cancer and the 8 case-control studies on talc ovarian cancer are on 9 equal footing? 10 A. I think -- again, using terminology like 11 "equal footing," it's -- I wouldn't really describe it 12 like that. 13 I think that case-control studies and cohort 14 studies are both well-established, well-accepted 15 methods for studying cancer epidemiology. There are 16 strengths and weaknesses to each design, as I have 17 indicated here. And some of them very -- some of the 18 strengths and weaknesses are very specific to this 19 exposure and outcome. 20 Q. Doesn't the body of talc ovarian cancer 21 literature that you've looked at for your MDL opinions 22 emphasize the importance of cohort data on the issue? 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I considered all of the 25 epidemiologic data; and when we look at the body of</p>

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<p>1 literature, more of the literature comes from 2 case-control studies than from cohort studies. So all 3 of the data are important. There just happen to be 4 more case-control studies than cohort studies. 5 BY MR. JAMES: 6 Q. But your testimony is that the cohorts are 7 not superior to the case-controls, and the 8 case-controls are not superior to the cohorts; 9 correct? 10 A. As I describe in my report -- the same page, 11 I say (as read): 12 "Rather than making a judgment 13 based only on the overall study 14 design, the evaluation and 15 interpretation of the findings of 16 the studies must consider the 17 strengths and weaknesses of the 18 individual studies." 19 And I think that I did consider that. 20 I considered strengths and weaknesses of the cohort 21 studies. I considered strengths and weaknesses of the 22 case-control studies. 23 Q. And you're not claiming that the study design 24 of these studies -- the cohort versus the 25 case-control -- one is superior to the other? You're</p>	<p>1 And it's the number of cases rather than the overall 2 size of the cohort that contributes to the statistical 3 power. And that doesn't address all the other 4 problems with that study. 5 But sometimes people will mistakenly say 6 these large studies -- you know, this large study, 7 40,000 people, and they didn't find an association. 8 But they're not looking into all the limitations of 9 that particular study. 10 BY MR. JAMES: 11 Q. Okay, Dr. Moorman, I'm going to object to the 12 nonresponsive nature of your answer. 13 A. I -- I think that I was responsive, but 14 please ask your question again. 15 Q. Okay. So the question that I asked you is 16 whether you are aware that the body of literature that 17 you've looked at has generally emphasized the 18 importance of cohort data on this topic. The answer 19 is yes or the answer is no. 20 MS. PARFITT: The answer is -- first, 21 I object to the question. And the witness has 22 answered the question several times. Your time. 23 You're on your clock. 24 BY MR. JAMES: 25 Q. Are you aware that the body of literature has</p>
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<p>1 not claiming that? 2 MS. PARFITT: Objection. Asked and 3 answered several times. 4 THE WITNESS: Right. I -- again, 5 I think that I have answered that, that they -- the 6 study designs are both well-accepted study designs; 7 they have advantages and disadvantages; and so you 8 have to look at some of the specific characteristics 9 of the individual studies. 10 BY MR. JAMES: 11 Q. And so the body of talc literature that 12 you've looked at, whether it be cohort studies, 13 meta-analyses, case-control studies, are you aware 14 that that body of literature has generally emphasized 15 the importance of cohort data on this topic? 16 MS. PARFITT: Objection. Misstates the 17 record -- scientific record. 18 THE WITNESS: I am aware -- I have read 19 some studies that mistakenly say that the cohort 20 studies, because they involve 40,000 or 60,000 people, 21 that they provide more of the evidence than all the 22 case-control studies, which are generally smaller. 23 However, just, again, to take the example of 24 the Gonzalez sisters study, that's a cohort with 25 40,000 people in it, but there were only 154 cases.</p>	<p>1 emphasized the importance of cohort data? Are you 2 aware of that? Yes or no? 3 MS. PARFITT: Objection. 4 THE WITNESS: I -- I disagree that -- 5 your characterization of it. 6 BY MR. JAMES: 7 Q. Then, the answer is no. 8 A. No. You asked am I aware -- 9 Q. The answer is yes or it's no, Dr. Moorman. 10 I have limited time to ask questions today. 11 Were you aware -- are you aware that the 12 body of literature on talc and ovarian cancer has 13 emphasized the importance of cohort data on this 14 topic? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: I don't think -- 17 MS. PARFITT: Asked and answered. 18 THE WITNESS: -- the statement is true. 19 I think that the -- 20 BY MR. JAMES: 21 Q. So then the answer is no. 22 MS. PARFITT: Stop. Let her answer. 23 THE WITNESS: No. You're asking me if 24 I'm aware -- 25 MS. PARFITT: Why do you ask her the</p>

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<p style="text-align: right;">Page 202</p> <p>1 same question?</p> <p>2 THE WITNESS: -- that this has</p> <p>3 emphasized that. And I don't think that is it at all.</p> <p>4 I think that the body of literature</p> <p>5 emphasizes again and again and again that of the</p> <p>6 roughly 25 to 30 studies, only three of them are</p> <p>7 cohort studies.</p> <p>8 It's part of the data on the topic, but it's</p> <p>9 just part of it. So to say that it has emphasized the</p> <p>10 importance of cohort data, I don't agree with that</p> <p>11 statement.</p> <p>12 BY MR. JAMES:</p> <p>13 Q. I marked the Houghton WHI study as</p> <p>14 Exhibit No. 25, and I'm going to hand you two copies.</p> <p>15 (Exhibit No. 25 was marked for identification.)</p> <p>16 THE WITNESS: Thank you.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. All right. Dr. Moorman, you see here in the</p> <p>19 abstract, the "Background" section of the paper, the</p> <p>20 authors of the WHI study in 2014 say that (as read):</p> <p>21 "The purpose of this analysis was</p> <p>22 to assess perineal powder use and</p> <p>23 risk of ovarian cancer</p> <p>24 prospectively."</p> <p>25 Correct?</p>	<p style="text-align: right;">Page 204</p> <p>1 exposure."</p> <p>2 Do you see where I read that?</p> <p>3 A. I do.</p> <p>4 Q. Okay. Again, do you agree with that</p> <p>5 statement as a general proposition?</p> <p>6 A. I would like to point out there are --</p> <p>7 potential reason, a potential for an overestimation.</p> <p>8 And in my own report, I acknowledge the potential for</p> <p>9 recall bias, and I go back to explain why I don't</p> <p>10 think that recall bias is a full explanation for this</p> <p>11 association.</p> <p>12 Q. Nevertheless, you will agree with me that the</p> <p>13 authors of this paper are acknowledging the importance</p> <p>14 of cohort data? Agree?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 THE WITNESS: As you would expect the</p> <p>17 investigators on a cohort study to do.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. And the answer was yes --</p> <p>20 A. Yes.</p> <p>21 Q. -- comma, as you would expect?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: Yes.</p> <p>24 MR. JAMES: I'm going to mark as the</p> <p>25 next exhibit the Gertig 2000 paper, which is</p>
<p style="text-align: right;">Page 203</p> <p>1 A. That is what it says, yes.</p> <p>2 Q. Okay. And if we look towards page 5, we see,</p> <p>3 at the top of the left-hand column, the authors there</p> <p>4 emphasize (as read):</p> <p>5 "The prospective nature of our</p> <p>6 study would eliminate the</p> <p>7 potential for recall bias."</p> <p>8 Do you see that?</p> <p>9 A. I do see that.</p> <p>10 Q. Do you agree with that general proposition?</p> <p>11 "Yes" or "no"?</p> <p>12 A. It eliminates the potential for recall bias.</p> <p>13 It does not eliminate the potential for inaccurate</p> <p>14 recall.</p> <p>15 Q. And if you look at page 4, it's the preceding</p> <p>16 set of sentences, the authors note -- quote -- at the</p> <p>17 bottom of the right column (as read):</p> <p>18 "One potential reason that</p> <p>19 case-control studies have found</p> <p>20 slight increases in risk is the</p> <p>21 potential for an overestimation of</p> <p>22 the true association due to recall</p> <p>23 bias, because the participants are</p> <p>24 aware of their ovarian cancer</p> <p>25 status when reporting powder</p>	<p style="text-align: right;">Page 205</p> <p>1 Exhibit No. 26.</p> <p>2 (Exhibit No. 26 was marked for identification.)</p> <p>3 BY MR. JAMES:</p> <p>4 Q. Again, this is the NHS 2000 paper; correct?</p> <p>5 A. That is correct.</p> <p>6 Q. And we see that in the abstract of this</p> <p>7 cohort paper, the authors state at the -- well, it's</p> <p>8 not in the abstract -- it's right above the "Methods"</p> <p>9 section, the authors state (as read):</p> <p>10 "Despite the relative consistency</p> <p>11 among studies, the limited</p> <p>12 supporting biologic evidence,</p> <p>13 together with the possibility of</p> <p>14 recall and selection bias in</p> <p>15 case-control studies, has raised</p> <p>16 questions about the plausibility</p> <p>17 of the association. We,</p> <p>18 therefore, prospectively examined</p> <p>19 the relationship between perineal</p> <p>20 talc use and ovarian cancer risk</p> <p>21 in a large cohort of US women."</p> <p>22 Do you see where I read that?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And again, methodologically, the authors of</p> <p>25 this cohort paper are emphasizing the importance of</p>

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<p style="text-align: right;">Page 206</p> <p>1 cohort data on the topic; correct?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 THE WITNESS: Yes. Again, they</p> <p>4 emphasize the importance of doing it prospectively, as</p> <p>5 you would expect the investigators on a cohort study</p> <p>6 to do.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Do you think that's just because there's some</p> <p>9 sort of subjective bias the authors of that cohort</p> <p>10 paper have towards cohorts? Do you think that's just</p> <p>11 their personal opinion?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 THE WITNESS: I have no way of knowing</p> <p>14 what their opinion is.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. A number of the meta-analyses that we've</p> <p>17 looked at today and that you looked at to inform your</p> <p>18 report have also talked about the benefits of cohort</p> <p>19 data. And I've asked that question before, and that's</p> <p>20 where we -- that's where we sort of ran into issues,</p> <p>21 so I'll just strike that question.</p> <p>22 If you can turn to -- back to the</p> <p>23 Penninkilampi study. And the Penninkilampi study is</p> <p>24 the recent meta-analysis that you cited 14 times in</p> <p>25 your report; correct?</p>	<p style="text-align: right;">Page 208</p> <p>1 again stressing the desire for cohort data on this</p> <p>2 topic; correct?</p> <p>3 MS. PARFITT: Objection. Misstates the</p> <p>4 evidence.</p> <p>5 THE WITNESS: When -- if we were to</p> <p>6 look at a cohort study where women were enrolled in</p> <p>7 the study early in their life when they started using</p> <p>8 talc and they were followed throughout their life and</p> <p>9 exposure information was updated throughout the period</p> <p>10 of follow-up and you followed them for 50 years, that</p> <p>11 would be a wonderful way -- a stronger design than to</p> <p>12 do a case-control study. So I could not disagree with</p> <p>13 that.</p> <p>14 But we're being asked to make a judgment on</p> <p>15 the data that we have here -- here and now, not</p> <p>16 something that's decades away.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. Do you agree that case-control studies are</p> <p>19 low-level evidence?</p> <p>20 A. No, I do not agree with that.</p> <p>21 Q. Do you know that the Penninkilampi authors</p> <p>22 referred to case-control studies as low-level</p> <p>23 evidence?</p> <p>24 A. I see that in their paper.</p> <p>25 Q. Do you --</p>
<p style="text-align: right;">Page 207</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 THE WITNESS: As stated below -- or</p> <p>3 stated above, I have cited it. I don't know how many</p> <p>4 times.</p> <p>5 BY MR. JAMES:</p> <p>6 Q. And meta-analyses also are what you refer to</p> <p>7 in your report as some of the strongest evidence;</p> <p>8 correct?</p> <p>9 A. Yes, that is correct.</p> <p>10 Q. Okay. And so the authors of this</p> <p>11 meta-analysis, on page 47 in the conclusion section,</p> <p>12 which we have looked at already, again note that</p> <p>13 case-control studies are "prone to recall bias";</p> <p>14 right?</p> <p>15 A. That's what it says, yes.</p> <p>16 Q. Okay. And then if you continue on past the</p> <p>17 section that we've already read -- and actually, it</p> <p>18 begins at the bottom of page 47 and carries to 48 --</p> <p>19 but the authors state (as read):</p> <p>20 "Additional epidemiologic evidence</p> <p>21 from prospective studies with</p> <p>22 attention to effects within</p> <p>23 ovarian cancer subtype is</p> <p>24 warranted."</p> <p>25 So here the authors of Penninkilampi are</p>	<p style="text-align: right;">Page 209</p> <p>1 A. I --</p> <p>2 Q. I'm sorry.</p> <p>3 A. I will disagree with that. It's -- just</p> <p>4 using the example of my own study, the AACES study.</p> <p>5 Of all the studies that have looked at talc and</p> <p>6 ovarian cancer, I believe that one is the one that has</p> <p>7 been most recently funded. So about 2009, 2010. It's</p> <p>8 quite an expensive study, and I can't imagine that the</p> <p>9 National Cancer Institute would have invested that</p> <p>10 much money in the study if they thought that we were</p> <p>11 only going to get low-level evidence.</p> <p>12 MS. PARFITT: Scott, we've been going</p> <p>13 about an hour and ten.</p> <p>14 You may want to keep going? Just let me</p> <p>15 know.</p> <p>16 THE WITNESS: I could use a break.</p> <p>17 MR. JAMES: May I finish this line? Is</p> <p>18 that okay with you?</p> <p>19 THE WITNESS: Yes.</p> <p>20 MR. JAMES: Everyone?</p> <p>21 MS. PARFITT: Sure.</p> <p>22 BY MR. JAMES:</p> <p>23 Q. Dr. Moorman, if you can turn with me to the</p> <p>24 Langseth study. It's Exhibit 22. And this will be</p> <p>25 the last series of questions, and then we'll take our</p>

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<p style="text-align: right;">Page 210</p> <p>1 break.</p> <p>2 A. Langseth -- okay. The exhibit number is</p> <p>3 incorrect.</p> <p>4 Q. Oh, you're right. And I'm going to fix that</p> <p>5 at break. Thank you.</p> <p>6 A. Okay.</p> <p>7 Q. If you turn with me to page -- well, you</p> <p>8 don't have to turn. It's page 358. It's the first</p> <p>9 page of the article. And, again, Langseth is one of</p> <p>10 the meta-analyses upon which you rely; correct?</p> <p>11 A. Correct.</p> <p>12 Q. And the meta-analyses authors here say, in</p> <p>13 the left-hand column at the bottom, the second</p> <p>14 sentence of the bottom paragraph, they say (as read):</p> <p>15 "In the cohort study, arguably the</p> <p>16 strongest study because of its</p> <p>17 partly prospective ascertainment</p> <p>18 of exposure, there was no</p> <p>19 association between cosmetic talc</p> <p>20 use and risk of all subtypes of</p> <p>21 ovarian cancer combined."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. You agree with the Langseth authors</p> <p>25 that the cohort study is arguably the strongest study</p>	<p style="text-align: right;">Page 212</p> <p>1 Q. And you cite Narod for your comments about</p> <p>2 power in the cohorts; correct?</p> <p>3 A. Yes.</p> <p>4 Q. Have you analyzed the calculations performed</p> <p>5 by Narod? Have you separately analyzed his</p> <p>6 calculations?</p> <p>7 A. No, I did not.</p> <p>8 Q. Have you considered any other commentaries or</p> <p>9 articles looking at the issue of power in the cohort</p> <p>10 studies in the talc ovarian cancer literature?</p> <p>11 A. I -- I'm trying to remember specifically. It</p> <p>12 seems like the Sister Study might have mentioned power</p> <p>13 as a limitation of their study because of the number</p> <p>14 of cases.</p> <p>15 Q. Did you consider -- let me just hand this to</p> <p>16 you. We already have it marked. It's the Berge</p> <p>17 article, which is Exhibit 21.</p> <p>18 A. Okay.</p> <p>19 Q. And I'm turning to page 253. And at the</p> <p>20 far -- the right column, top paragraph, and halfway</p> <p>21 down through that paragraph, the authors state</p> <p>22 (as read):</p> <p>23 "It should be noted that the</p> <p>24 cohort studies included in the</p> <p>25 meta-analyses comprised a total of</p>
<p style="text-align: right;">Page 211</p> <p>1 because of its prospective nature?</p> <p>2 A. I really can't say that I agree with that,</p> <p>3 because the prospective aspect of it is certainly a</p> <p>4 positive for the study, but the way they did exposure</p> <p>5 assessment kind of weakened the study.</p> <p>6 So I think that there were some very well</p> <p>7 done case-control studies, so I wouldn't necessarily</p> <p>8 say this was the strongest study.</p> <p>9 MR. JAMES: And now is a good time for</p> <p>10 the break.</p> <p>11 THE WITNESS: Okay.</p> <p>12 MR. JAMES: Thank you.</p> <p>13 THE VIDEOGRAPHER: Going off record at</p> <p>14 3:02 p.m.</p> <p>15 (Recess taken from 3:02 p.m. to 3:16 p.m.)</p> <p>16 THE VIDEOGRAPHER: Back on record at</p> <p>17 3:16 p.m.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. Dr. Moorman, on page 25 of your report, you</p> <p>20 make a comment about power and the cohort studies;</p> <p>21 correct?</p> <p>22 A. Can you --</p> <p>23 Q. It's the bottom of first paragraph, where you</p> <p>24 cite the Narod article.</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 213</p> <p>1 429 cases of ovarian cancer</p> <p>2 exposed to genital talc and 943</p> <p>3 unexposed cases. The statistical</p> <p>4 power of the meta-analysis of</p> <p>5 these cohort studies to detect a</p> <p>6 relative risk of 1.25, similar to</p> <p>7 the result of meta-analyses of</p> <p>8 case-control studies, was .99.</p> <p>9 Thus low power of cohort studies</p> <p>10 cannot be invoked as an</p> <p>11 explanation of the heterogeneity</p> <p>12 of results."</p> <p>13 You see where I was reading?</p> <p>14 A. I do.</p> <p>15 Q. Have you considered this portion of the Berge</p> <p>16 article before?</p> <p>17 A. I have looked at this article, and I have</p> <p>18 considered all aspects of it, as I did all of the</p> <p>19 other meta-analyses and articles.</p> <p>20 Q. You did not cite the Berge article with</p> <p>21 regard to the issue of power in your report; correct?</p> <p>22 MS. PARFITT: Objection. Form.</p> <p>23 THE WITNESS: No, I -- I did not.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. Okay. And why is that?</p>

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<p>1 A. I can't cite any specific reason.</p> <p>2 Q. Is that because this conflicts with your</p> <p>3 litigation opinion on power?</p> <p>4 MS. PARFITT: Objection. Form.</p> <p>5 THE WITNESS: No. I -- I don't -- that</p> <p>6 was not my reason, no.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Do you have any reason to disagree with the</p> <p>9 power analysis set forth in the Berge paper?</p> <p>10 A. I -- I don't have a reason to disagree with</p> <p>11 the power issue, but I think that it's only one part</p> <p>12 of the picture, that there are other factors that</p> <p>13 could contribute to differences in the findings</p> <p>14 between the cohort studies and the case-control</p> <p>15 studies.</p> <p>16 Q. With respect to this precise power</p> <p>17 calculation in the Berge paper, do you have any</p> <p>18 criticisms of this power calculation?</p> <p>19 A. They do not provide much detail on how they</p> <p>20 calculated it, so there's really -- I can't say if</p> <p>21 they did it correctly or not. But I -- I just can't</p> <p>22 comment on it. It's just a single sentence there.</p> <p>23 Q. Similar to the Narod sentence that you</p> <p>24 reviewed?</p> <p>25 A. I --</p>	<p>1 but with respect to the issue of follow-up -- it's the</p> <p>2 paragraph above the Narod comment.</p> <p>3 Do you see where I am?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And there, we talk about -- excuse me.</p> <p>6 There, you talk about the follow-up for the cohort</p> <p>7 studies; correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And with respect to the NHS follow-up,</p> <p>10 there is where you report 14 years of follow-up;</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. And as we discussed earlier today, that does</p> <p>14 not account for the additional ten years of data as</p> <p>15 reflected by the Gates 2010 paper; correct?</p> <p>16 A. What I am referring here, I'm describing the</p> <p>17 three cohort studies in the most recent meta-analyses</p> <p>18 and what they reported in that meta-analysis --</p> <p>19 Q. Understood.</p> <p>20 A. Okay.</p> <p>21 Q. So you're referring there to the</p> <p>22 Penninkilampi meta-analysis; correct?</p> <p>23 A. I believe that is the case. Let me check the</p> <p>24 reference. Yes.</p> <p>25 Q. So Penninkilampi reports the 14 years of</p>
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<p>1 Q. Let me rephrase it if it helps.</p> <p>2 Did you separately assess the Berge --</p> <p>3 excuse me -- the power calculation in either the Narod</p> <p>4 article or the Berge article?</p> <p>5 A. If I may go back to my report for just a</p> <p>6 moment.</p> <p>7 Q. Sure.</p> <p>8 A. I think that this statement that I have</p> <p>9 here -- I'm -- I think my intent in my report was</p> <p>10 indicating that the lack of statistical significance</p> <p>11 in the individual studies was a power concern.</p> <p>12 Berge was talking about the statistical</p> <p>13 power for the combined studies. So I think that there</p> <p>14 is some distinction there between what I'm referring</p> <p>15 to individual studies versus what Berge is describing</p> <p>16 as the power of the combined analysis.</p> <p>17 Q. Well, Berge is saying that the low power of</p> <p>18 cohort studies cannot be invoked as an explanation for</p> <p>19 the heterogeneity of results.</p> <p>20 Do you agree or disagree with that</p> <p>21 statement?</p> <p>22 A. When they are combining them, I -- I don't</p> <p>23 disagree with that. I think there are other reasons</p> <p>24 that can explain the heterogeneity.</p> <p>25 Q. On page 25, we've touched upon this already,</p>	<p>1 follow-up; correct?</p> <p>2 A. I believe so.</p> <p>3 Q. And we know that the Penninkilampi paper did</p> <p>4 not include the additional 10 years of follow-up as</p> <p>5 reflected by the Gates 2010 paper; correct?</p> <p>6 A. Yes. We have already -- you've already asked</p> <p>7 and I've already answered that.</p> <p>8 Q. And then the next one you discuss is the WHI</p> <p>9 study where you are reporting Penninkilampi's</p> <p>10 reporting of 12.4 years of follow-up; correct?</p> <p>11 A. That is correct.</p> <p>12 Q. And do you know that the follow-up period in</p> <p>13 the WHI -- do you know that the WHI asked about</p> <p>14 duration of talc use?</p> <p>15 A. May I go back to that study?</p> <p>16 Q. Sure.</p> <p>17 A. Do you --</p> <p>18 Q. It's 25.</p> <p>19 A. Yes, they describe in their exposure</p> <p>20 assessment, that they did ask about duration of use</p> <p>21 using five categories from less than a year all the</p> <p>22 way up to 20 or more years.</p> <p>23 Q. And so we know that they -- they followed the</p> <p>24 study participants for, according to Penninkilampi,</p> <p>25 12.4 years. But, in addition to that, they also asked</p>

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<p>1 about the -- study participants about their prior 2 duration of usage; correct? 3 A. They asked about that, but I think that one 4 has to consider some of the caveats that go along with 5 that. These -- may I continue? 6 These women, they report that they were, on 7 average, 63 years of age when they -- at baseline, so 8 at the start of enrollment in the cohort. So they 9 were asking them to recall an exposure that went back, 10 for many women, that probably started in their teens 11 or twenties. So there was certainly the possibilities 12 of some inaccurate recall because they were asking 13 them to recall an exposure that went back quite a few 14 years. 15 Another consideration with this study is 16 they excluded roughly -- let's see -- the cohort 17 was -- they started off with 90-some-thousand women in 18 the cohort, and they excluded any history of any women 19 with cancer at baseline, which is appropriate to do, 20 but the potential concern about that is, if there were 21 talc users who had developed ovarian -- or had 22 developed ovarian cancer before the follow-up began, 23 that would never be captured. 24 MR. JAMES: Okay. Dr. Moorman, just 25 very respectfully, I'm going to have to object to the</p>	<p>1 excuse me -- page 26, you discuss updating exposure 2 information in the cohort studies. 3 A. Yes. 4 Q. Do you have any basis to dispute the accuracy 5 of the reported talc use at the time it was initially 6 ascertained in the cohort studies? 7 A. The accuracy of the reported talc use at the 8 time that they started follow-up in the cohorts. 9 Q. Correct. 10 A. I believe that, when you are asking people to 11 recall exposures that occurred over a long period of 12 time, there will be some inadvertent inaccuracies. 13 Q. And are you saying with respect to questions 14 about duration? 15 A. It could be with ever use or with duration. 16 Some women who used it might have forgotten and never 17 reported it. So that's just kind of an inherent 18 problem anytime you ask someone to recall exposures, 19 particularly if they might have occurred decades ago. 20 Q. Is that true for the case-control studies as 21 well? 22 A. Yes. In my report, I indicate that -- I make 23 the distinction between recall bias and inaccurate 24 recall and indicate that inaccurate recall -- 25 specifically on page 21, make the distinction between</p>
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<p>1 nonresponsive portion of the answer. 2 BY MR. JAMES: 3 Q. So the question that I asked is not the 4 question that you ended up answering. 5 A. I did answer your question, I believe. 6 Q. Okay. I didn't ask you for your critiques of 7 the WHI. I asked you about the follow-up issue. 8 Okay? Do we need to look at the question again? 9 I asked -- my question is: 10 "Question: But in addition to that, 11 they also asked about -- the study 12 participants about their prior 13 duration of usage; correct?" 14 A. And I answered it but thought that there were 15 important relevant considerations. 16 MR. JAMES: Can we go off the record 17 for a second -- 18 MS. PARFITT: Yes. 19 MR. JAMES: -- please? 20 THE VIDEOGRAPHER: Off record at 3:29. 21 (Discussion off the record.) 22 THE VIDEOGRAPHER: Back on record at 23 3:31 p.m. 24 BY MR. JAMES: 25 Q. On page 25 of your report, Dr. Moorman --</p>	<p>1 recall bias and inaccurate recall that is difficult -- 2 inaccurate recall and exposure that is difficult to 3 remember with precision. 4 And that's an issue with any type of study 5 when you're asking people to recall past exposures. 6 Q. And transitioning to the topic that you 7 brought up, which is the recall bias. We can stay on 8 page 216 your report. 9 A. Yes. 10 Q. And there, you address -- at the bottom 11 paragraph, you say that (as read): 12 "Recall bias, which theoretically 13 could result in the bias estimate 14 of the relative risk, must be 15 considered." 16 Do you see where I am? 17 A. I do. 18 Q. And you cite three situations where recall 19 bias would be a "particular threat" to a study's 20 validity; right? 21 A. Yes. 22 Q. And with -- let's walk through those three 23 together. 24 The first is -- the first threat that you 25 identify is "if the exposure of interest is one that</p>

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<p>1 could be considered sensitive"; right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And then you address that reason in</p> <p>4 turn on the next page, on page 22 of your report?</p> <p>5 A. Yes.</p> <p>6 Q. And you state there that (as read):</p> <p>7 "In regard to the situation,</p> <p>8 genital talc use would 'not be</p> <p>9 considered a particularly</p> <p>10 sensitive topic.'"</p> <p>11 Right?</p> <p>12 A. That's what I state in my report, yes.</p> <p>13 Q. Okay. And what basis do you have for that</p> <p>14 statement? Do you cite to anything? Have you</p> <p>15 conducted any studies to support that statement? What</p> <p>16 scientific basis do you have for that statement?</p> <p>17 A. This is based on my professional judgment,</p> <p>18 based on years and years of doing studies where we</p> <p>19 collect data, getting feedback from interviewers. In</p> <p>20 our studies, we ask about a lot of personal things,</p> <p>21 you know, their menstrual history, their contraceptive</p> <p>22 history, those kind of things.</p> <p>23 And I have never gotten the impression that</p> <p>24 these were things that women considered sensitive and</p> <p>25 did not want to reveal, whereas when you get into</p>	<p>1 them, or any reason why a woman, if she's telling you</p> <p>2 her whole pregnancy and menstrual history, why she</p> <p>3 would feel embarrassed about her use of genital talc.</p> <p>4 Q. And do you have any empirical data to support</p> <p>5 that opinion?</p> <p>6 A. I am unaware of any empirical data that</p> <p>7 specifically addresses that.</p> <p>8 Q. Okay. The second situation you identify on</p> <p>9 page 21 and then discuss on page 22 is if -- is if the</p> <p>10 study hypotheses are known to the study subjects or</p> <p>11 interviewers.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And your analysis is on page 22.</p> <p>15 What did you do to evaluate this factor?</p> <p>16 A. Whether the study hypotheses are known to the</p> <p>17 study subjects or interviewers?</p> <p>18 Q. Correct. With respect to the talc ovarian</p> <p>19 cancer literature.</p> <p>20 A. Okay. Again, this is based on my experience</p> <p>21 in having done epidemiologic studies for many years.</p> <p>22 As I state here, it's standard practice in</p> <p>23 epidemiologic research where we're not discussing the</p> <p>24 hypotheses with the interviewers. We're asking a lot</p> <p>25 of questions. Some thought to increase risk; some</p>
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<p>1 other topics, say -- like, I give the example of</p> <p>2 induced abortion, that, I have heard from some of our</p> <p>3 interviewers, that sometimes that evokes strong</p> <p>4 emotions in the women.</p> <p>5 And so I think that, you know, there are</p> <p>6 some exposures that are sensitive, as I describe, that</p> <p>7 women might be hesitant to report. And I contrast</p> <p>8 that with things that are personal but not</p> <p>9 particularly sensitive.</p> <p>10 When a woman has agreed to be in a study,</p> <p>11 she knows that we're going to be asking some of these</p> <p>12 questions. And I have never heard any comments from</p> <p>13 any of the interviewers in the many studies I've done</p> <p>14 that this was a question that women felt uncomfortable</p> <p>15 with.</p> <p>16 Q. Do you acknowledge the possibility that a</p> <p>17 person's use of a cosmetic talcum powder in their</p> <p>18 genital region could be viewed by some as a sensitive</p> <p>19 topic?</p> <p>20 A. I -- again, I -- I kind of make the</p> <p>21 distinction between something that is personal -- and</p> <p>22 we ask them a lot of personal questions, but it's --</p> <p>23 I don't see any aspect of that that would seem</p> <p>24 particularly sensitive, why someone might be</p> <p>25 embarrassed or feel that someone was going to judge</p>	<p>1 thought to decrease risk. It's standard that you</p> <p>2 would not really discuss the hypotheses with the</p> <p>3 interviewers.</p> <p>4 And, similarly, when we invite or ask women</p> <p>5 to be in our studies, we will tell them that, you</p> <p>6 know, it is a study of ovarian cancer, but we're not</p> <p>7 telling them which factors we think might be</p> <p>8 associated with increased risk and which ones might be</p> <p>9 associated with decreased risk.</p> <p>10 Q. To support this statement, did you conduct</p> <p>11 any post-interview interviews?</p> <p>12 A. Can you restate that? Tell me -- I'm not</p> <p>13 sure what you're asking.</p> <p>14 Q. So to determine if study hypotheses were</p> <p>15 known to the study subjects at the time that they were</p> <p>16 asked the questions, there would be methods or ways to</p> <p>17 which you could find that out; correct?</p> <p>18 A. We -- I'm thinking about it. I have never</p> <p>19 known that to be -- I've never known a study that has</p> <p>20 done that.</p> <p>21 In one breast cancer study, at the end of</p> <p>22 the interview, we asked the women if they had any</p> <p>23 ideas about what caused breast cancer. And, you know,</p> <p>24 we thought it might maybe raise some new ideas, but we</p> <p>25 found that it was largely -- we didn't see anything</p>

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<p>1 that was usable. I think that the most common 2 response was that women thought it was stress. So -- 3 Q. But you don't have any evidence of anything 4 similar being done in the talc ovarian cancer 5 literature; correct? 6 A. Not to my knowledge. 7 Q. At the bottom of page 22, and then carrying 8 over through 23, you cite to the Lanza study; correct? 9 A. That's correct. 10 Q. And you cite Lanza for the proposition 11 that -- to provide "further evidence that recall bias 12 in case-control studies does not inevitably lead to an 13 overestimate." 14 Do you see where I was reading? It's at the 15 bottom of 22. 16 A. Yes. Yes, I see where you're reading. 17 Q. Lanza did not pertain to talc and ovarian 18 cancer; correct? 19 A. As I state in my report, yes. It's looking 20 at a variety of meta-analyses that looked at both 21 case-control studies and cohort studies. And the 22 point of that paper was to determine if recall bias 23 seemed to lead to a consistently increased risk. And 24 their conclusion, as I state in here, there's no 25 significant difference in the effect estimates between</p>	<p>1 are that the estimates did not differ between 2 case-control and prospective or retrospective cohort 3 studies; correct? 4 A. Where are you reading, please? 5 Q. I'm in the "Results" section. 6 A. Okay. Yes. 7 Q. And then they say, "Heterogeneity was also 8 low," below that; right? 9 A. Yes. 10 Q. Again, if I'm understanding this paper 11 correctly, the situation for talc and ovarian cancer 12 is completely different, isn't it? Where we do have 13 heterogeneity between the prospective studies and the 14 retrospective case-control studies; right? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: We have one example in 17 the talc and the -- and the ovarian cancer -- in the 18 meta-analyses, they did note some heterogeneity 19 between the cohort studies and the case-control 20 studies. 21 I think that the point that I was trying to 22 get with that is in the observational studies, there's 23 always concern, as several of these people have -- as 24 several of the meta-analyses and other papers have 25 reported, that the stronger association due to --</p>
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<p>1 the case-control and cohort studies, suggesting that 2 the study design didn't have an important impact on 3 the conclusions of the meta-analyses. 4 MR. JAMES: Okay. I marked Lanza as 5 Exhibit 27. I'll hand you two copies. 6 (Exhibit No. 27 was marked for identification.) 7 BY MR. JAMES: 8 Q. And so Lanza concerns therapeutic 9 interventions; correct? 10 A. Yes. 11 Q. And isn't -- and correct me if I'm wrong 12 here, but looking at Lanza, isn't what Lanza doing is 13 they're comparing the odds ratios reached in both the 14 case-control studies and in the prospective studies on 15 a completely different body of literature; right? 16 A. It is not dealing with talc and ovarian 17 cancer, if that is your question. 18 Q. And they're looking at whether the results of 19 the case-control studies on that separate body of 20 literature and the results of the prospective cohort 21 studies on that separate body of literature reached 22 different results; right? 23 A. Yes. 24 Q. Okay. And so the author's conclusions in the 25 abstract here are -- which you note in your report --</p>	<p>1 among the case-control studies was due to some kind of 2 recall bias. 3 So the point is, if it was recall bias, you 4 would expect to see that case-control studies always 5 had higher estimates than the cohort studies; and this 6 study is making the point that in this wide variety of 7 interventions that they looked at, that doesn't seem 8 to be the case at all. Okay. 9 BY MR. JAMES: 10 Q. So, again, this study is saying, "Look, the 11 results of case-control studies and the results of 12 prospective cohort studies on these therapeutic 13 interventions are similar, same ballpark, and so thus, 14 we can conclude that recall bias in this body of 15 literature must not be a big deal." 16 Is that a layman's fair way to describe the 17 results of this paper? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: Yeah. I -- I mean, 20 I think that it's one part of the -- I think that, 21 overall, that's a pretty fair summary of the point 22 that this paper is making. So... 23 BY MR. JAMES: 24 Q. And if you acknowledge that in the talc 25 ovarian cancer literature, there is a disparity</p>

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<p>1 between the retrospective case-control studies and the 2 prospective cohort studies, then Lanza isn't really 3 applicable at all, is it? 4 MS. PARFITT: Objection. 5 THE WITNESS: It is -- I think that it 6 is very applicable because it's trying to get at the 7 recall -- is recall bias -- is that a problem in 8 case-control studies that is going to inevitably lead 9 to higher risk estimates than what you would get in 10 cohort studies? 11 And as we have seen in these articles, we 12 see recall bias is frequently cited as a potential 13 reason that we saw stronger associations in 14 case-control studies than in cohort studies. 15 And I think this paper is really pointing 16 out that that's not inevitable, that you're always 17 going to have higher estimates with case-control 18 studies than cohort studies. 19 Specifically in relation to the 20 heterogeneity between the cohort studies and the 21 case-control studies in talc, I think that we have to 22 consider other biases that may be operating. 23 BY MR. JAMES: 24 Q. I mean, the justification for the Lanza 25 conclusions is that the results in the two study</p>	<p>1 Q. If you're looking at Lanza objectively, 2 doesn't it say exactly the opposite of what you're 3 saying here, Doctor? 4 I mean, again, the justification for Lanza 5 is the results are the same, and so recall bias isn't 6 a problem. But that justification doesn't exist in 7 the world of talc ovarian cancer. 8 That will be my last question on that. 9 A. No. I think that this addresses the recall 10 bias in the -- you know, I acknowledge it doesn't 11 directly address talc and ovarian cancer in this 12 paper; but it does address this -- this commonly-cited 13 thing that, you know, recall bias in case-control 14 studies could lead to higher risk estimates. And it's 15 saying that's not necessarily the case always. 16 Q. I promised that was my last question -- 17 A. Okay. 18 Q. -- so we'll move on. 19 The third factor that you discuss as a 20 particular threat for recall bias is if there is 21 considerable media attention. 22 Do you see where I've returned back to on 23 page 22? 24 21 is where you -- 21 through 22 is where 25 you lay out the three reasons. At the top of 22, you</p>
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<p>1 designs are pretty much the same. So these two study 2 designs didn't reach different results. And so in 3 this body of literature, we don't really need to be 4 worried about recall bias. Recall bias was not 5 operating to create a disparity of results in this 6 body of literature. 7 But, in contrast, in the talc ovarian cancer 8 world, there is a disparity in the results by study 9 design; right? 10 A. We've already acknowledged there is some 11 heterogeneity in results. Is it due to recall bias? 12 Is it -- do we have to assume that recall bias is in 13 play here and that explains the higher -- or the 14 stronger associations generally reported in the 15 case-control studies. 16 And this article is addressing one -- one 17 potential bias, the recall bias. And I don't -- 18 I think that it provides support that we cannot just 19 do a knee-jerk reaction of "case-control studies, they 20 have the potential for recall bias, that leads to 21 higher estimates, and therefore, these studies are 22 biased." 23 There are other biases in play in the cohort 24 studies that I think are very plausible explanations 25 for why there might be some differences.</p>	<p>1 say "considerable media attention." 2 A. Yes. 3 Q. And then you evaluate the media attention 4 factor on the following page; right? 5 A. On page 23, yes. 6 Q. On 23, you say that, for the media attention 7 concern, you say in the middle of the first full 8 paragraph (as read): 9 "The concern is not relevant to 10 the vast majority of the studies 11 as virtually all the data 12 collection in the epidemiologic 13 studies of talc and ovarian cancer 14 occurred prior to such 15 litigation." 16 Do you see that? 17 A. Yes, I do. 18 Q. And you agree that media attention is not 19 limited to litigation; correct? 20 A. Yes. 21 Q. Did you undertake any effort to analyze the 22 extent of publicity or media attention to the talc 23 ovarian cancer issue prior to 2014? 24 A. I did not do any specific analysis of that. 25 I personally was unaware of any media attention on</p>

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<p>1 this topic prior to the litigation. 2 Q. Then I believe on page 23, you go on to 3 discuss the Schildkraut 2016 paper; correct? 4 A. Yes. 5 Q. Okay. And if we can pull that back out. It 6 is the exhibit -- did I mark it? 7 MS. PARFITT: I don't think so. 8 MR. JAMES: Okay. I'll mark it as the 9 next one, so you don't have to fish for it here. It's 10 Exhibit 28. 11 (Exhibit No. 28 was marked for identification.) 12 MR. JAMES: Which is the Schildkraut 13 2016 paper. I'll hand you two copies. 14 BY MR. JAMES: 15 Q. And so we touched upon this a bit earlier, 16 Dr. Moorman, where we talked about the phraseology 17 where you say the association was "attenuated but not 18 eliminated." 19 Do you recall that exchange we had earlier? 20 THE WITNESS: Yes, I do. 21 BY MR. JAMES: 22 Q. Okay. And in this 2016 paper, again, you, 23 among the authors, compared the odds ratios for talc 24 and ovarian cancer for participants before 2014 and 25 for participants after 2014; correct?</p>	<p>1 Q. And you -- I believe this table reflects -- 2 though I'm still looking for it, and maybe you can 3 help me with it -- but the data in this table reflects 4 that pre-2014 interviewees reported talc usage at the 5 rate of 36 percent, and post-2014 interviewees 6 reported rates -- excuse me, reported usage at the 7 rate of 51 percent. 8 A. Yes, I see that in the table. 9 Q. And so that's a significant disparity in 10 reported usage rates; would you agree with that? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: Clearly, it is what it 13 is. It's 36 percent as -- versus 51 percent. Okay. 14 BY MR. JAMES: 15 Q. And so we have your paper here showing that 16 before 2014, before the onset of the litigation, you 17 had study participants reporting talc usage at a lower 18 rate; right? 19 A. Than -- yes. 20 Q. And if you isolated the association analysis 21 to those -- to that group, you also have a 22 non-statistically significant association; correct? 23 A. And again, when you stratify -- we've already 24 covered that. I acknowledge that prior to 2014, it 25 was not statistically significant. We also indicated</p>
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<p>1 A. Correct. 2 Q. And if we look at page 1414 -- I'm looking 3 for my place here. 4 If you look at Table 2, Dr. Moorman, you see 5 there where you have broken out the data on interview 6 date after 2014; right? 7 A. Yes. 8 Q. And then above that is the interview date 9 before 2014; correct? 10 A. Yes. 11 Q. And we see that the odds ratio here for 12 interview date after 2014 is 2.91; correct? 13 A. That is correct. 14 Q. That's well in excess of any odds ratio 15 reported in any of the meta-analyses; correct? 16 A. For the overall summary odds ratio, yes. 17 Q. And before 2014, we see that the odds ratio 18 is a 1.19 that is not statistically significant, which 19 is what we discussed earlier; correct? 20 A. Yes, we discussed that earlier. 21 Q. And you also report in this article a 22 distinction between the pre-2014 interviewees and the 23 post-2014 interviewees based upon their reported talc 24 usage; right? 25 A. Yes.</p>	<p>1 certainly in the range of what many other studies have 2 seen. But when you stratify like that, you are 3 getting into smaller sample sizes. So there's 4 statistical significance that -- the fact that it's no 5 longer statistically significant is not all that 6 surprising. 7 Q. Have you seen the Trabert editorial that 8 followed the publication of the Schildkraut article? 9 A. I'm sure that I have read it at some point, 10 but -- 11 Q. Okay. I'm going to -- I'm sorry. 12 A. -- please, let's -- I haven't looked at it in 13 quite some time. 14 Q. So I'm going to mark as Exhibit 29 an 15 editorial by Britton Trabert entitled "Body Powder and 16 Ovarian Cancer Risk -- What is the Role of Recall 17 Bias?" 18 I'll hand you two copies. 19 (Exhibit No. 29 was marked for identification.) 20 BY MR. JAMES: 21 Q. Dr. Moorman, does this editorial look 22 familiar to you? Have you seen it before? 23 A. Yes, I have seen it before. 24 Q. Have you ever spoken with or communicated 25 with Britton Trabert about this editorial?</p>

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<p>1 A. No, I have not.</p> <p>2 Q. And you see that in the right-hand column,</p> <p>3 about midway down, Dr. Trabert refers to the data</p> <p>4 points that we were just discussing; correct?</p> <p>5 A. Yes.</p> <p>6 Q. And if you look to the second page of the</p> <p>7 editorial, Trabert reports, at the last paragraph of</p> <p>8 the article (as read):</p> <p>9 "The current study highlights the</p> <p>10 concern over recall bias in</p> <p>11 case-control studies, particularly</p> <p>12 once an exposure becomes the</p> <p>13 subject of considerable media</p> <p>14 coverage."</p> <p>15 Do you see where I was reading that?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Do you agree with Dr. Trabert's concerns</p> <p>18 about media coverage impacting the results of the</p> <p>19 Schildkraut study?</p> <p>20 A. I -- I think that the investigators on our</p> <p>21 study, they had that concern. That's why we did those</p> <p>22 analyses. So...</p> <p>23 Q. So do you acknowledge the possibility that</p> <p>24 the results of the 2016 study may reflect recall bias</p> <p>25 in the study?</p>	<p>1 possibility of recall bias, but I think that we looked</p> <p>2 at the other side of the coin as well.</p> <p>3 Q. And can you tell me where you're reading that</p> <p>4 sentence from, Dr. Moorman?</p> <p>5 A. Let's see. The -- it is on page 1416, the</p> <p>6 right-hand column, and it's about -- probably about</p> <p>7 eight or nine lines down.</p> <p>8 So I think that this sentence -- or this</p> <p>9 whole paragraph gives a pretty balanced assessment of</p> <p>10 the data, that we thoughtfully considered the issue of</p> <p>11 recall bias, but we also considered that maybe the</p> <p>12 greater publicity led to -- was kind of a memory</p> <p>13 trigger that led to more accurate recall.</p> <p>14 Q. And in your report, do you include a caution</p> <p>15 on the Schildkraut 2016 study about the potential for</p> <p>16 recall bias based upon the 2014 pre- and post-data?</p> <p>17 A. I -- let's see. We have discussed that</p> <p>18 section of the report a couple of times already. And</p> <p>19 I state that there is the possibility that recall bias</p> <p>20 could have led to the higher odds ratios when</p> <p>21 including women interviewed during the time when there</p> <p>22 was more media attention focused on this exposure.</p> <p>23 Q. And you're at page 23; right?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And then you conclude the middle</p>
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<p>1 A. In this discussion -- if I may take just a</p> <p>2 moment to --</p> <p>3 Q. Certainly.</p> <p>4 A. Okay. You know, I think that</p> <p>5 Dr. Schildkraut, who did the major writing of this</p> <p>6 article -- and I think all of the coauthors were in</p> <p>7 agreement -- that we were concerned about the recall</p> <p>8 bias. As I said, that was some of the reason for</p> <p>9 doing those analyses.</p> <p>10 I think that it's also important to point</p> <p>11 out here the other possibility. There may have been</p> <p>12 some recall bias. But she also makes the statement</p> <p>13 that (as read):</p> <p>14 "It is possible that the lawsuit</p> <p>15 sharpened memories of body powder</p> <p>16 use and improved the accuracy of</p> <p>17 reported use for both cases and</p> <p>18 controls interviewed in 2014 or</p> <p>19 later."</p> <p>20 I think that that goes to say that anytime</p> <p>21 someone -- you know, there's some memory trigger, it</p> <p>22 could have made actually more accurate recall.</p> <p>23 So we --</p> <p>24 Q. And Dr. --</p> <p>25 A. I'm sorry. So we acknowledge both the</p>	<p>1 paragraph with the statement that -- the "attenuated</p> <p>2 but not eliminated" statement. But I'm not going to</p> <p>3 ask about that again. But you go on in that sentence</p> <p>4 to say (as read):</p> <p>5 "The association is not due</p> <p>6 entirely to recall bias."</p> <p>7 Do you see that phrasing that I just read?</p> <p>8 A. Yes.</p> <p>9 Q. So are you conveying in that wording that you</p> <p>10 think some portion of the odds ratio that you are</p> <p>11 seeing in these case-control studies that you're</p> <p>12 relying on or the meta-analyses that you're relying</p> <p>13 on, that some portion of that odds ratio is</p> <p>14 attributable to recall bias?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 THE WITNESS: I think that probably</p> <p>17 every meta-analysis published, probably every</p> <p>18 case-control study that was published, we acknowledge</p> <p>19 this as a -- recall bias is a potential bias. But</p> <p>20 I think that we went on to give evidence --</p> <p>21 I explained why I did not think that it was a complete</p> <p>22 explanation.</p> <p>23 Can we completely rule out any possibility</p> <p>24 of recall bias? I don't know that we can do it. But</p> <p>25 I think that as -- for some of the reasons</p>

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<p>1 I articulated.</p> <p>2 I know that Dan Cramer in his 2016 paper</p> <p>3 also went into great detail considering the issue of</p> <p>4 recall bias. And I don't think that we can attribute</p> <p>5 this association to recall bias.</p> <p>6 BY MR. JAMES:</p> <p>7 Q. Can you cite to any publication that has</p> <p>8 analyzed the literature and ruled out recall bias --</p> <p>9 MS. PARFITT: Objection.</p> <p>10 BY MR. JAMES:</p> <p>11 Q. -- as a method -- as a basis for the elevated</p> <p>12 odds ratio of the 1.2 to 1.3 that you're citing in</p> <p>13 your report?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: Okay. I went back to the</p> <p>16 Dan Cramer article, and I'm hoping that I'm recalling</p> <p>17 that particular article, the date of it, accurately.</p> <p>18 But he did analyze the data and the degree of</p> <p>19 misclassification that would have had to occur for</p> <p>20 recall bias to account for this association. He gave</p> <p>21 other reasons for why it seemed unlikely that recall</p> <p>22 bias would account for this association.</p> <p>23 So I think he did a pretty thorough</p> <p>24 analysis -- a thoughtful analysis of it.</p> <p>25</p>	<p>1 Q. Okay. Dr. Moorman, on page 11 of your</p> <p>2 report, you talk about -- this is where you begin your</p> <p>3 analysis of the Bradford Hill factors.</p> <p>4 A. Yes.</p> <p>5 Q. And are you there with me?</p> <p>6 A. Yes, I am.</p> <p>7 Q. Okay. You say, in page 11 -- you have a</p> <p>8 section titled "Strength and consistency of the</p> <p>9 association"; correct?</p> <p>10 A. Correct.</p> <p>11 Q. You say in the first sentence that strength</p> <p>12 and consistency are "deeply intertwined." Correct?</p> <p>13 A. Yes.</p> <p>14 Q. Can you cite to any publication where you</p> <p>15 have combined the analysis of strength and consistency</p> <p>16 before?</p> <p>17 A. I -- I can't cite any publication that</p> <p>18 specifically addresses that, no.</p> <p>19 Q. Can you cite any published authority that</p> <p>20 states these two Bradford Hill criteria are deeply</p> <p>21 intertwined?</p> <p>22 A. I -- I think that as I was -- I cannot cite a</p> <p>23 published authority.</p> <p>24 I think that, again, this is based on when</p> <p>25 I was looking at these and how I was weighting these</p>
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<p>1 BY MR. JAMES:</p> <p>2 Q. Can you cite any other publications other</p> <p>3 than the Cramer 2016 paper, sitting here today, that</p> <p>4 have addressed recall bias in the fashion that you</p> <p>5 just described?</p> <p>6 A. The Cramer article is the one that I -- that</p> <p>7 comes to mind as the one that addressed it most</p> <p>8 thoroughly.</p> <p>9 Q. Have you ever published the three factors</p> <p>10 that you have addressed with regard to recall bias?</p> <p>11 A. The three factors are --</p> <p>12 Q. Sure. So --</p> <p>13 A. Okay.</p> <p>14 Q. Within your report, you -- we just walked</p> <p>15 through the three factors that you've considered, the</p> <p>16 three factors that you deemed to be a particular</p> <p>17 threat to case-control studies for recall bias;</p> <p>18 correct? We just walked through those three?</p> <p>19 A. Yes.</p> <p>20 Q. Have you ever published those three in any</p> <p>21 article or journal or anything else?</p> <p>22 A. I have not published that. That is just</p> <p>23 based on my general epidemiologic knowledge from doing</p> <p>24 this type of research and teaching in this field for</p> <p>25 the last couple of decades.</p>	<p>1 considerations.</p> <p>2 Q. Do you agree that strength is an important</p> <p>3 criteria in and of itself?</p> <p>4 A. I think that the strength of the association</p> <p>5 is an important criteria, but I think that we also</p> <p>6 have to bear in mind that as -- that there are many</p> <p>7 well-established causal associations that are</p> <p>8 certainly not in the order of magnitude of what we</p> <p>9 see, for example, with smoking and lung cancer.</p> <p>10 Q. Do you think the criteria of strength is met</p> <p>11 with the talc and ovarian cancer literature?</p> <p>12 A. When -- as I go through my report, I give</p> <p>13 numerous examples of well-accepted causal associations</p> <p>14 that are of a similar magnitude as what we see with</p> <p>15 talc and ovarian cancer, and so I think that the data</p> <p>16 are strong enough.</p> <p>17 Q. And I think that I'm going to ask my question</p> <p>18 again.</p> <p>19 A. Okay.</p> <p>20 Q. Do you think that the criteria of strength is</p> <p>21 met with the talc and ovarian cancer literature?</p> <p>22 A. Okay --</p> <p>23 MS. PARFITT: Objection. Asked and</p> <p>24 answered.</p> <p>25 Try again, Dr. Moorman.</p>

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<p>1 THE WITNESS: Okay. So, once again, 2 I -- we have to use -- we have to be careful of -- 3 Dr. Hill did not refer to these as "criteria," but 4 guidelines or viewpoints I think was the terminology 5 he used. And I do think that the criteria of strength 6 has been met. 7 BY MR. JAMES: 8 Q. Can you cite to a single study in the talc 9 ovarian cancer literature that refers to the 10 association as a strong association? 11 A. I -- I cannot, off the top of my head, think 12 of anyone that refers to it as a strong association. 13 I do, once again, want to say that we see evidence of 14 causal associations of similar magnitude; so I think 15 that it is strong enough to be a causal association. 16 Q. Do you understand that a number of the papers 17 that you have cited in your reference list or 18 materials-considered list refer to the association as 19 weak? 20 MS. PARFITT: Objection. 21 THE WITNESS: Which papers are you 22 referring to specifically? 23 BY MR. JAMES: 24 Q. If an author in the talc ovarian cancer 25 literature has referred to the association as a weak</p>	<p>1 MR. JAMES: It hasn't been answered. 2 MS. PARFITT: It's been asked. 3 THE WITNESS: I don't think that we 4 have any actual definition of what is modest. I think 5 that the association is what it is, a 25 to 30 percent 6 increased risk. 7 BY MR. JAMES: 8 Q. As an epidemiologist, you're not capable of 9 discerning whether an association is modest or not 10 modest? 11 MS. PARFITT: Objection. 12 THE WITNESS: As I have said before, 13 I don't think there is any clear definition of that 14 adjective. 15 BY MR. JAMES: 16 Q. Is there a definition in the epidemiologic 17 community of a weak association? Are you able to 18 understand what that would mean in the epidemiologic 19 community? 20 A. Once again, there is no -- to my knowledge, 21 there is nothing that would say, you know, an odds 22 ratio in this range is weak, this is modest, this is 23 moderate, this is strong. 24 And, again, going back to Bradford Hill, he 25 certainly emphasizes that there are some associations</p>
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<p>1 association, would you agree or disagree with that 2 characterization? 3 MS. PARFITT: Object to form. 4 THE WITNESS: I would disagree with 5 the -- I would disagree with that. 6 BY MR. JAMES: 7 Q. If an author or authors in the talc ovarian 8 cancer literature have referred to the association as 9 modest, would you agree or disagree with that? 10 A. Once again, I think that many of the risk 11 factors that we are considering are not going to be 12 the odds ratios of 10 or greater that we saw with 13 this. 14 And when you read the papers written by 15 Dr. -- by Bradford Hill, he certainly makes the point 16 that some weaker associations can certainly be real. 17 Q. So is this a weaker association? 18 A. Weaker is in comparison to what? It's not -- 19 it's weaker than smoking and lung cancer. It is -- 20 I keep making the point that it -- we fully 21 acknowledge that it is not a tenfold increased risk. 22 It's a 25 to 30 percent increased risk. 23 Q. Would you call the association modest? 24 MS. PARFITT: Objection. Asked and 25 answered.</p>	<p>1 that are not in the magnitude of smoking and lung 2 cancer, but they are certainly real. 3 Q. And I think you're conflating -- or you're 4 misunderstanding my question, because you're answering 5 the question about whether the association is real or 6 not real, and my question for you is whether the 7 association is weak, modest, or strong. 8 How would you characterize it? 9 A. And I would -- as I have said, there is no 10 absolute terminology that would say what is a weak 11 association, what is modest, and what is strong. So 12 I think that it is more accurate just to describe it 13 as it is, a 25 to 30 percent increased risk of ovarian 14 cancer. 15 Q. Well, in assessing the Bradford Hill factors 16 or considerations or criteria -- in assessing that and 17 determining whether the association is strong or not 18 strong, as an epidemiologist, don't you need to be 19 capable of determining whether the association is 20 strong or not strong? 21 A. Once again, it is an adjective that is not 22 well defined. And -- 23 Q. And do you -- I'm sorry. 24 A. I -- I -- I keep going back to I think that 25 the association that we see is what it is, a 25 to</p>

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<p>1 30 percent increased risk. It is consistent with 2 other factors that we consider causal associations. 3 They have a similar strength of association. 4 Q. And I do -- I do intend to go to that very 5 next topic next -- 6 A. Okay. 7 Q. -- but in assessing strength, what I'm asking 8 is whether, in all of the papers that you've cited, 9 when the epidemiologists that you've cited refer to 10 the association as weak or modest or small, is that 11 terminology that you can accept, or is that 12 terminology that you reject? 13 A. I say that it is terminology that is 14 imprecise. What one would consider modest, someone 15 else might consider moderate. It's imprecise 16 terminology. 17 Q. And certainly in the epidemiology world, if 18 you have a small or modest or weak association, what 19 you're saying is that that doesn't bar a causal 20 conclusion. But wouldn't you agree with me that if 21 the association is small or modest or weak, it makes 22 the other considerations more important? 23 MS. PARFITT: Objection. 24 THE WITNESS: I think that all of the 25 considerations are important. It's --</p>	<p>1 A. Yes. 2 Q. And these associations that you've listed, 3 you have concluded are generally accepted to be 4 causal; correct? 5 A. I think so, yes. 6 Q. And below that, you state that the IARC has 7 reached a causal conclusion with respect to each of 8 these associations; is that right? 9 A. Yes, that is what I state. 10 Q. And so to state that, are you saying that all 11 five of these exposures and associations have been 12 classified by IARC as Category 1? 13 A. I don't recall if -- I don't recall the 14 classifications, specifically, for all of these. 15 Q. Well, to say that the IARC has made a causal 16 judgment on these associations, you are necessarily 17 saying that they have classified these associations as 18 Category 1; correct? 19 A. I -- you know, I answered the question. 20 I don't recall which IARC category that each of these 21 exposures is right off the top of my head. 22 Q. But do you say in the report that they are 23 judged to be causal by IARC; correct? 24 A. I do say that in my report. 25 Q. And IARC has not judged talc ovarian cancer</p>
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<p>1 BY MR. JAMES: 2 Q. Do you agree that, with a small association, 3 there's more concern for recall bias? 4 MS. PARFITT: Objection. 5 THE WITNESS: I think that with a 6 smaller association, there is more concern that it 7 could be due to bias from various reasons. 8 BY MR. JAMES: 9 Q. Can you cite to any scientific agency or 10 organization that has described the talc ovarian 11 cancer association as strong? 12 A. I do not recall anyone describing it that 13 way. 14 Q. Okay. And then we will turn now to page 12 15 of your report, Dr. Moorman, where you cite a number 16 of other exposures. 17 A. Yes. 18 Q. And do you see where I am? 19 A. Yes. 20 Q. And you say on page 12 that (as read): 21 "Well-accepted exposure to these 22 associations have relative risks 23 of similar magnitude and are 24 generally accepted to be causal." 25 Do you see where I was reading?</p>	<p>1 to be a causal association, has it? 2 A. As we have discussed several times today, 3 they describe it as possibly carcinogenic. 4 Q. Can you cite to any publication that assesses 5 the strength of an epidemiologic association by 6 considering "similar magnitude" odds ratios from 7 unrelated exposures to diseases? 8 A. I -- off the top of my head, I can't cite any 9 such publication. 10 Q. Have any scientific agencies that have looked 11 at this issue assessed strength of the talc ovarian 12 cancer relationship by considering similar magnitude 13 associations of unrelated exposures to diseases? 14 A. I know that in the Health Canada report, they 15 went through assessing the strength of the 16 association. I don't recall if they kind of 17 considered it in relation to other exposures that have 18 a similar magnitude of association. 19 Q. With regard to the associations that you have 20 identified on page 12, did you review the entire body 21 of scientific and medical literature pertaining to 22 those associations? 23 A. In -- let's see. Since when I cited these, 24 I did not go through the same level of detail like 25 I have done for the talc and ovarian cancer.</p>

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<p>1 The oral contraceptive use and breast cancer 2 that I cite, I was part of a team of researchers that 3 did a systematic review and meta-analysis of oral 4 contraceptives in relation to ovarian cancer as well 5 as breast cancer and some other cancers. 6 The other ones, again, I did not go in -- 7 did not review the body of literature in the same 8 detail as I did the talc and ovarian cancer. 9 Q. Did you assess, in any of these bodies of 10 literature, the risks for recall bias? 11 A. I did not. 12 Q. Did you consider, in these bodies of 13 literature, biologic mechanism for these five 14 exposures that you've identified? 15 A. I considered biologic mechanism, again, not 16 in the level of detail with the talc and ovarian 17 cancer. 18 Q. Did you assess them in a manner sufficient to 19 which you would opine in a published article or a 20 litigation report about the evidence supporting 21 causation? 22 A. I'm reading your question again. 23 Q. So am I. 24 A. I'm not sure. 25 Q. For these five exposures and diseases that</p>	<p>1 BY MR. JAMES: 2 Q. So in your report, when you are assessing 3 strength, and you discuss the fact that there are 4 similar magnitude odds ratios from other exposures 5 upon which one could conclude causation, you do not 6 also remark that there are similar magnitude ratios 7 upon one which could not conclude causation. 8 Why is that? Why did you lay out the 9 analysis this way? 10 A. What I was trying to do here is to make the 11 point that an association in the range of a 25 to 12 30 percent increased risk is something that there are 13 multiple examples of this being generally accepted as 14 a causal association. 15 I -- it was not my intent to describe the 16 entire universe of exposures and some that might be in 17 this range. 18 Q. There are certainly examples that you didn't 19 cite in the 1.2 to 1.3 range that are not causal; 20 right? 21 A. Did you have something specific in mind that 22 you are -- 23 Q. I'm asking you, actually. 24 Did you just go searching for similar 25 magnitude ratios upon which one could reach a</p>
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<p>1 you've cited on page 12, did you assess the body of 2 scientific and medical literature and evidence in a 3 manner sufficient to which you would feel comfortable 4 offering an opinion in the published literature or in 5 a litigation report about causation? 6 A. I think that I have answered the question 7 repeatedly that I did not do it in the detail that 8 I did the talc and ovarian cancer. If I were to put 9 in published literature or a litigation report, 10 I would want to make sure that I had done it as 11 absolutely thoroughly as possible. 12 Q. Your comparison of the odds ratios to these 13 five exposures -- you acknowledge that there are 14 exposures that you have not identified in your report 15 that are in the 1.2 to 1.3 range that are not causal 16 or have not proven to be causal; correct? 17 MS. PARFITT: Objection. Form. 18 THE WITNESS: I acknowledge that -- of 19 course, that there are reports of exposures that have 20 reported relative risk in this range, and it could 21 either be something that was associated with another 22 risk factor and it was not the causal factor or the 23 level of evidence was not adequate. Maybe people -- 24 there were fewer articles, people have not gone 25 through the whole evaluation of the causal criteria.</p>	<p>1 causation conclusion? 2 A. I -- I think that I was trying to get at that 3 is this association strong enough to be causal? And 4 we have evidence from these other exposures that, yes, 5 it's certainly possible. 6 The point is that you do not -- or you do 7 not dismiss an association of 1.25 or 1.3 as it 8 couldn't possibly be causal. We have evidence to 9 suggest that it -- there are many examples of it. 10 Q. But in your report, Dr. Moorman, you're not 11 just not dismissing it. You're not just using the 12 similar magnitude odds ratios to not dismiss the 13 possibility that this is a real association. You're 14 using the similar magnitude ratios in an effort to 15 ascribe strength to the association; correct? 16 A. Right. I am saying that I think this is 17 strong enough to be a real association, and I think 18 that we have other examples of similar magnitude 19 associations that are generally accepted as causal 20 associations. 21 Q. But if there are other odds ratios for other 22 exposures to diseases that you did not identify in 23 your report in the 1.2 to 1.3 range that are not 24 causal, then the magnitude ratio that you have here in 25 the top ovarian cancer literature, in that instance,</p>

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<p>1 is not strong enough to support causation?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 BY MR. JAMES:</p> <p>4 Q. I'll just restate it because it's confusing.</p> <p>5 A. Yeah, it is.</p> <p>6 Q. To support strength in your report, why do</p> <p>7 you select only similar magnitude ratios that, by your</p> <p>8 estimation, are Category 1 -- by your estimation, have</p> <p>9 been declared by IARC to be causal associations? Why</p> <p>10 do you only select associations by which one has -- by</p> <p>11 which IARC has concluded causation? Why don't you</p> <p>12 also acknowledge that there are associations of a</p> <p>13 similar magnitude that don't support causation?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: I'm not really sure --</p> <p>16 I'm still not really sure what you're getting at with</p> <p>17 this question.</p> <p>18 I think that I was trying to make the point</p> <p>19 that the association we see here is strong enough to</p> <p>20 be accepted as a causal association. I'm not -- I'm</p> <p>21 not saying that every association of this magnitude</p> <p>22 has gone through the same process of assessing all of</p> <p>23 the Bradford Hill viewpoints and have come to the same</p> <p>24 conclusion, but I am saying that we have multiple</p> <p>25 examples of where an association of this magnitude is</p>	<p>1 Do you see where I'm reading that?</p> <p>2 A. Yes.</p> <p>3 Q. There, are you referring to epidemiologic</p> <p>4 literature?</p> <p>5 A. What -- you're taking one sentence and --</p> <p>6 I think that I discussed what I considered related to</p> <p>7 the passive smoke exposure and lung cancer and</p> <p>8 described it in more detail on page 13, the first full</p> <p>9 paragraph.</p> <p>10 Q. And is it fair to say that that body of</p> <p>11 evidence that you're referring to there is the</p> <p>12 epidemiologic literature?</p> <p>13 A. Yes.</p> <p>14 Q. You're not referring there to any sort of</p> <p>15 mechanistic studies or plausibility studies or</p> <p>16 anything like that; correct?</p> <p>17 A. No. I was looking at -- basically, I was</p> <p>18 comparing the two -- or the meta-analyses for the two</p> <p>19 topics.</p> <p>20 Q. On page 14, Dr. Moorman, you discuss the</p> <p>21 "prevalence of exposure."</p> <p>22 Do you see where I am? It's the --</p> <p>23 A. It's about halfway down?</p> <p>24 Q. Yeah, second full paragraph.</p> <p>25 A. Yes.</p>
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<p>1 causal.</p> <p>2 MS. PARFITT: Scott, is this a breaking</p> <p>3 point or no?</p> <p>4 MR. JAMES: How long have we been</p> <p>5 going?</p> <p>6 MR. FARIES: About an hour and 15.</p> <p>7 MS. BRENNAN: Yeah, we've been going</p> <p>8 about an hour and 15.</p> <p>9 MR. JAMES: Sure. Are we ready for a</p> <p>10 break?</p> <p>11 MS. PARFITT: Sure. Just a short one,</p> <p>12 yeah. Thank you.</p> <p>13 THE VIDEOGRAPHER: Going off the record</p> <p>14 at 4:33 p.m.</p> <p>15 (Recess taken from 4:33 p.m. to 4:46 p.m.)</p> <p>16 THE VIDEOGRAPHER: Back on record at</p> <p>17 4:47 p.m.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. Dr. Moorman, on page 13 to 14 of your report,</p> <p>20 and really the top of page 14, you have a sentence</p> <p>21 stating that (as read):</p> <p>22 "The evidence for talc and ovarian</p> <p>23 cancer is as significant as for</p> <p>24 passive smoke exposure and lung</p> <p>25 cancer."</p>	<p>1 Q. And you say that it's critical to consider</p> <p>2 the prevalence of exposure in conjunction with</p> <p>3 considering strength; correct?</p> <p>4 A. I say (as read):</p> <p>5 "It's critical to consider the</p> <p>6 prevalence of the exposure in the</p> <p>7 population when evaluating its</p> <p>8 public health impact."</p> <p>9 Q. Before that, you say "in conjunction with the</p> <p>10 strength of the association." Right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Do you think that the prevalence of</p> <p>13 exposure in the population, that that impacts your</p> <p>14 analysis on whether an association is strong or not</p> <p>15 strong?</p> <p>16 A. I think that the way that I stated it here</p> <p>17 is, you know, as an epidemiologist, a public health</p> <p>18 professional, I'm interested in the public health</p> <p>19 impact and how many cases of disease could be</p> <p>20 attributable to this exposure.</p> <p>21 So I go through and describe that factor</p> <p>22 that has a stronger association but is less common in</p> <p>23 the population could have potentially less public</p> <p>24 health impact than a risk factor that is -- doesn't</p> <p>25 have as high an odds ratio but you have many more</p>

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<p>1 exposed people in the population.</p> <p>2 Q. Moving on to consistency, Dr. Moorman, is</p> <p>3 consistency met on this body of literature?</p> <p>4 A. I do feel that consistency is met.</p> <p>5 Q. And on page 14, you -- I think it's page 14.</p> <p>6 Yes. In the first full paragraph, you discuss your --</p> <p>7 you see the last sentence of that paragraph, where you</p> <p>8 say (as read):</p> <p>9 "This observation has been quite</p> <p>10 consistent with findings</p> <p>11 replicated in studies conducted by</p> <p>12 different teams of investigators</p> <p>13 in different geographic locations</p> <p>14 and different race ethnic groups</p> <p>15 over a span of several decades."</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Is that reflective of -- is that the basis</p> <p>19 upon which you conclude consistency is met?</p> <p>20 A. It is part of the basis of it. I think that,</p> <p>21 when we look at the overall meta-analyses, we look at</p> <p>22 the direction of the effect in all the studies and of</p> <p>23 these, like, 27 different studies, like, 90 percent of</p> <p>24 them show an increased -- or an odds ratio greater</p> <p>25 than 1.</p>	<p>1 cancer?</p> <p>2 A. They -- if we can go back to them, we see</p> <p>3 that there are multiple studies from the Nurses'</p> <p>4 Health Study, and then the Houghton study. They are</p> <p>5 showing a relative risk in most cases, I think, 1.12</p> <p>6 to 1.19. And, again, we have discussed some of the</p> <p>7 biases that might result in an attenuation of the</p> <p>8 association.</p> <p>9 And so I acknowledge that, with the</p> <p>10 exception of the serous invasive cancer in one of the</p> <p>11 studies, the associations have not been statistically</p> <p>12 significant, but they are certainly kind of in the</p> <p>13 direction of -- as the case-control studies.</p> <p>14 Q. Doctor, let's turn back briefly to the</p> <p>15 Houghton study. It's Exhibit 25.</p> <p>16 Are you with me?</p> <p>17 Dr. Moorman, if we look at the Houghton</p> <p>18 study on the first page in the results section of the</p> <p>19 abstract. Do you see where I'm looking?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. The authors there, they report</p> <p>22 every-use odds ratio as a 1.06.</p> <p>23 Do you see that?</p> <p>24 A. I do see that --</p> <p>25 Q. Okay. I'm running out of time, Dr. Moorman,</p>
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<p>1 When we look at epidemiologic data, for</p> <p>2 reasons that we have discussed earlier today, it is</p> <p>3 very uncommon for every single study to reach the same</p> <p>4 conclusion. Some are going to have higher risk; some</p> <p>5 are going to be lower risk. And the level of</p> <p>6 consistency seen here, where virtually every study is</p> <p>7 showing an odds ratio greater than 1, I consider that</p> <p>8 quite consistent.</p> <p>9 Q. You understand that Bradford Hill, when he</p> <p>10 describes consistency, he talks about consistency</p> <p>11 across study design.</p> <p>12 Were you aware of that?</p> <p>13 A. Yes, I am. And I actually do -- the way that</p> <p>14 I described consistency, where even, you know -- two</p> <p>15 of the three cohort studies -- and we've already</p> <p>16 discussed the concerns I have about the Sister Study,</p> <p>17 which is really quite an outlier when we look at this</p> <p>18 whole body of literature. But both the Houghton study</p> <p>19 and the Nurses' Health Study, they are consistent in</p> <p>20 terms of the direction of the effect. And we have</p> <p>21 discussed the statistical significance at all.</p> <p>22 But in terms of the direction of the effect,</p> <p>23 I think that it is consistent.</p> <p>24 Q. So is your position that the cohorts</p> <p>25 demonstrate an association between talc and ovarian</p>	<p>1 so I really am going to ask you to answer my precise</p> <p>2 question.</p> <p>3 Do you see where the authors, they say</p> <p>4 there -- the authors say that it's "not associated</p> <p>5 with risk of ovarian cancer compared with never-use."</p> <p>6 Do you see that?</p> <p>7 A. Yes, that is what they state.</p> <p>8 Q. Okay. And 1.06 is -- again, it's not a</p> <p>9 statistically significant association; correct?</p> <p>10 A. With the confidence interval that they</p> <p>11 report. That's what tells you whether or not it's</p> <p>12 statistically significant. And with that confidence</p> <p>13 interval, no, it is not statistically significant.</p> <p>14 Q. And it's also very close to the null, isn't</p> <p>15 it?</p> <p>16 A. Yes. It's the 1.06, yes.</p> <p>17 Q. And the conclusion of the authors here is</p> <p>18 that (as read):</p> <p>19 "Perineal powder use does not</p> <p>20 appear to influence ovarian cancer</p> <p>21 risk."</p> <p>22 Correct?</p> <p>23 A. That's what they state, yes.</p> <p>24 Q. So this is one of the cohorts that you're</p> <p>25 talking about today; correct?</p>

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<p>1 A. Right. And --</p> <p>2 Q. And the authors here conclude that there's</p> <p>3 not an association between ovarian cancer risk and</p> <p>4 perineal talc use, don't they?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: Okay. Yes, I acknowledge</p> <p>7 that's their conclusion. And I think that -- I'm</p> <p>8 sorry -- the data that I was referring to comes from</p> <p>9 Table 3. And I, again, acknowledge that it was not</p> <p>10 statistically significant, but he said only genital</p> <p>11 powder use -- which is mostly what we're</p> <p>12 considering -- it had a hazard ratio of 1.4 or 1.3 --</p> <p>13 I'm sorry -- 1.14 or 1.13.</p> <p>14 And so, again, it's in the direction of</p> <p>15 effect, and, as we have discussed, biases could have</p> <p>16 led to some attenuation.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. Are you saying that you believe that there's</p> <p>19 consistency among -- or between the case-control</p> <p>20 studies and the cohort studies in the talc ovarian</p> <p>21 cancer literature?</p> <p>22 A. I am saying that -- as I have pointed out</p> <p>23 here and with also the Nurses' Health Study, I am</p> <p>24 saying that there is consistency in the direction of</p> <p>25 the effect that they observed, and acknowledging that</p>	<p>1 right around 1. About half the studies have odds</p> <p>2 ratios greater than 1; about half have odds ratios</p> <p>3 less than 1. So in that case, I would say there is no</p> <p>4 consistency.</p> <p>5 I contrast it with this where, when you look</p> <p>6 at the forest plots from the meta-analyses, nearly all</p> <p>7 of the studies have odds ratios greater than 1.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. And you're including in that testimony the</p> <p>10 cohort studies?</p> <p>11 A. Yes.</p> <p>12 Q. Odds ratios that are not statistically</p> <p>13 significant, in your mind, demonstrate consistency</p> <p>14 by -- among study design. Is that your testimony?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: I'm sorry --</p> <p>17 BY MR. JAMES:</p> <p>18 Q. Your testimony here today is that the results</p> <p>19 reached by the cohort studies and the case-control</p> <p>20 studies are consistent. Is that your testimony?</p> <p>21 A. My testimony, as I have stated repeatedly,</p> <p>22 that there is a great deal of consistency in the</p> <p>23 direction of the effect, that nearly all of the</p> <p>24 studies report an odds ratio greater than 1. And</p> <p>25 I acknowledge that not all studies are statistically</p>
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<p>1 these were not statistically significant findings.</p> <p>2 Q. So even though the authors report that</p> <p>3 there's not an association, you're claiming today that</p> <p>4 the cohort studies are consistent with the</p> <p>5 case-control studies in finding a association?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 THE WITNESS: I think that I have</p> <p>8 answered the question already that, in terms of the</p> <p>9 direction of the effect, that the Houghton study for</p> <p>10 the genital powder use and as well as some of the data</p> <p>11 from the Nurses' Health Study, it is consistent that</p> <p>12 there -- the odds ratio is greater than 1.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. So as long as the odds ratio, even if it's</p> <p>15 statistically insignificant, exceeds 1, then you are</p> <p>16 claiming that that's reflective of an association that</p> <p>17 is consistent with the case-control studies?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: I am saying that there is</p> <p>20 consistency in the direction of the effect.</p> <p>21 If I may clarify. If you look at something</p> <p>22 like alcohol use and ovarian cancer, which is a fact,</p> <p>23 which overall there seems to be little association</p> <p>24 between alcohol and ovarian cancer, if you look at the</p> <p>25 meta-analyses from there, the overall estimate is</p>	<p>1 significant, but I'm just saying that the direction of</p> <p>2 the effect is very consistent.</p> <p>3 Q. And we talked earlier today about the Berge</p> <p>4 paper; correct?</p> <p>5 A. Yes, we did.</p> <p>6 Q. And they have performed an analysis for</p> <p>7 heterogeneity on the -- by study design; right?</p> <p>8 A. If I could go back to that.</p> <p>9 Q. Sure.</p> <p>10 A. Okay.</p> <p>11 Q. Dr. Moorman, if we look at the abstract of</p> <p>12 the paper, at the beginning, this is the point we</p> <p>13 discussed earlier. Here, the authors say (as read):</p> <p>14 "The heterogeneity of results by</p> <p>15 study design detracts from a</p> <p>16 causal interpretation."</p> <p>17 Correct?</p> <p>18 A. That is the statement that they make in their</p> <p>19 abstract, yes.</p> <p>20 Q. Okay. And then we looked earlier also at the</p> <p>21 Figure 2; correct?</p> <p>22 A. Yes, we did.</p> <p>23 Q. Okay. And, again, that reflects an analysis</p> <p>24 of the cohorts as compared to the case-controls;</p> <p>25 correct?</p>

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<p>1 A. Yes.</p> <p>2 Q. If you look at page 253 of the Berge article,</p> <p>3 and we look at the right column, the first -- the</p> <p>4 second full paragraph, the authors there state</p> <p>5 (as read):</p> <p>6 "The fact that the association</p> <p>7 between genital talc use and risk</p> <p>8 of ovarian cancer is present in</p> <p>9 case-control but not in cohort</p> <p>10 studies can be attributed to bias</p> <p>11 in the former type of studies."</p> <p>12 Do you see that?</p> <p>13 A. I do see what they say.</p> <p>14 I -- I think that they are not considering</p> <p>15 that there is also potential bias in the cohort</p> <p>16 studies. They say "bias in the former type of</p> <p>17 studies," not acknowledging the biases in the cohort</p> <p>18 studies.</p> <p>19 When you look at these data for the cohort</p> <p>20 studies, you look at the Gonzalez study, which again,</p> <p>21 I have referred to it as kind of an outlier with its</p> <p>22 relative risk of .73, there are many problems with</p> <p>23 that study. They assessed exposure in the past 12</p> <p>24 months. The level of exposure is very different than</p> <p>25 many of the other studies.</p>	<p>1 noted in some meta-analysis and</p> <p>2 reviews, there are considerations</p> <p>3 about those that should be taken</p> <p>4 into account."</p> <p>5 Q. Do you believe that there are inconsistencies</p> <p>6 in the literature with regard to dose-response? Yes</p> <p>7 or no.</p> <p>8 A. I think that, yes, that there -- that across</p> <p>9 the studies, some have found a dose-response, some</p> <p>10 have not.</p> <p>11 Q. At the bottom of page 30, you say that</p> <p>12 (as read):</p> <p>13 "When considering the studies that</p> <p>14 examine dose-response associations</p> <p>15 considering both dose and</p> <p>16 frequency to estimate the total</p> <p>17 number of applications of talc,</p> <p>18 the majority did find significant</p> <p>19 trends of higher risk with more</p> <p>20 lifetime applications of talc."</p> <p>21 Do you see that, where I read that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And so for that proposition, you're</p> <p>24 citing to eight studies. If you look at the</p> <p>25 footnotes, you would agree with me that that's</p>
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<p>1 And so part of the heterogeneity by study</p> <p>2 design could be attributed to this Gonzalez study that</p> <p>3 has very significant biases.</p> <p>4 Q. If other experts for Plaintiffs in this MDL</p> <p>5 litigation have conceded that there is not consistency</p> <p>6 between the cohorts and the case-controls, then you</p> <p>7 would differ with those experts; correct?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: I have --</p> <p>10 MS. PARFITT: Misstates the evidence.</p> <p>11 Thank you.</p> <p>12 THE WITNESS: I have answered the</p> <p>13 question, I think I've answered it repeatedly, why</p> <p>14 I think that the aspect of consistency is met.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. Okay. On dose-response -- on page 30, you</p> <p>17 include discussion of dose-response in the literature.</p> <p>18 A. Yes.</p> <p>19 Q. And you acknowledge in your report that there</p> <p>20 are inconsistencies in reported dose-response;</p> <p>21 correct?</p> <p>22 A. I -- what I state is (as read):</p> <p>23 "While the inconsistency in</p> <p>24 reported dose-response trends for</p> <p>25 talc and ovarian cancer have been</p>	<p>1 reflective of eight studies cited; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And you're saying that five of the eight</p> <p>4 studies that have looked at dose and frequency</p> <p>5 together did find significant trends; correct?</p> <p>6 A. Yes.</p> <p>7 Q. Among those studies that you cite for that</p> <p>8 proposition that the majority of those studies reflect</p> <p>9 a dose-response, you cited to the Mills study;</p> <p>10 correct?</p> <p>11 A. I believe so.</p> <p>12 MS. PARFITT: And, Dr. Moorman, you</p> <p>13 have your binder in front of you as well if you need</p> <p>14 it.</p> <p>15 MR. JAMES: Okay. I'm going to mark</p> <p>16 Mills as Exhibit 30.</p> <p>17 (Exhibit No. 30 was marked for identification.)</p> <p>18 BY MR. JAMES:</p> <p>19 Q. I'm going to hand you two copies.</p> <p>20 And, again, this is one of the papers you've</p> <p>21 cited for the proposition that there's a dose-response</p> <p>22 in the majority of studies that have looked at</p> <p>23 frequency times duration; correct?</p> <p>24 A. Okay. Yes.</p> <p>25 Q. And we're looking at Table 2 as the relevant</p>

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<p>1 table with the data; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And if you look at Table 2, you go down to</p> <p>4 the cumulative use category, it says "frequency times</p> <p>5 duration"; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And if I'm looking at this correctly,</p> <p>8 Dr. Moorman, doesn't the data in that table reflect an</p> <p>9 actual decrease in the odds ratio for the highest</p> <p>10 exposure category?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 THE WITNESS: It is -- the highest</p> <p>13 category, yes, does report an odds ratio of 1.06.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. And based upon that, is it fair to say that</p> <p>16 this paper reflects a dose-response when measuring</p> <p>17 frequency times duration?</p> <p>18 A. They looked at the -- they did a test for</p> <p>19 trend, and we have a p-value of .051, so right at</p> <p>20 borderline statistically significant. Some people</p> <p>21 would argue that you should never use two decimal</p> <p>22 points for p-values. But nonetheless, it's -- the</p> <p>23 trend test was what I was referring to here, that it</p> <p>24 was right at borderline statistical significance.</p> <p>25 Q. And if you look at page 463 of the article,</p>	<p>1 Q. And they're not just acknowledging that</p> <p>2 there's not a perfect linear increase; they're saying</p> <p>3 that there's no dose-response for cumulative use.</p> <p>4 A. They say there is not a clear dose-response.</p> <p>5 I think -- you know, again, that's what they say. My</p> <p>6 conclusion here was, again, based on the test for</p> <p>7 trend that they did. I don't think that it was</p> <p>8 inaccurate, what I said here.</p> <p>9 Q. Another paper that you cite for the majority</p> <p>10 claim is the Terry 2013 paper; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And do you know what the authors concluded in</p> <p>13 that paper about dose-response for cumulative use?</p> <p>14 A. May we look at that article?</p> <p>15 Q. Sure. It's Exhibit 24. And if we look at</p> <p>16 the abstract first together, the abstract says, the</p> <p>17 second sentence from the bottom (as read):</p> <p>18 "Among genital powder users, we</p> <p>19 observed no significant trend in</p> <p>20 risk with increasing number of</p> <p>21 lifetime applications assessed in</p> <p>22 quartiles."</p> <p>23 Did I read that correctly?</p> <p>24 MS. PARFITT: In the abstract?</p> <p>25 THE WITNESS: I'm sorry, I wasn't quite</p>
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<p>1 the third full paragraph down -- 463 in the left</p> <p>2 column -- the authors -- this is in the authors'</p> <p>3 words. They say (as read):</p> <p>4 "As in other studies, the present</p> <p>5 study did not find a clear</p> <p>6 dose-response based on duration of</p> <p>7 use or cumulative use."</p> <p>8 Do you see that?</p> <p>9 A. Right. And they go on to say that -- again,</p> <p>10 I was basing what I said here based on their test for</p> <p>11 trend, and -- and I think they do acknowledge that in</p> <p>12 that category where they had relatively few exposed</p> <p>13 cases, they didn't -- it was not a perfectly linear</p> <p>14 association.</p> <p>15 Q. So the authors are concluding that there's</p> <p>16 not dose-response for cumulative use; correct?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. Yes or no? That's what the authors conclude</p> <p>20 in the text that we just read together?</p> <p>21 A. I -- what we read -- yes. I'm trying --</p> <p>22 let's see.</p> <p>23 Yeah, I think that they are acknowledging</p> <p>24 that it was not a perfect linear increase. My report</p> <p>25 was basing it on the test for trend that they did.</p>	<p>1 there with you. Could you --</p> <p>2 BY MR. JAMES:</p> <p>3 Q. Understood. No worries.</p> <p>4 A. Okay.</p> <p>5 Q. So second sentence from the bottom of the</p> <p>6 abstract, the author's conclusions on dose-response</p> <p>7 are as follows (as read):</p> <p>8 "Among genital powder users, we</p> <p>9 observed no significant trend in</p> <p>10 risk with increasing number of</p> <p>11 lifetime applications assessed in</p> <p>12 quartiles."</p> <p>13 A. That's what they describe, and --</p> <p>14 Q. I just asked, is that -- did I read that</p> <p>15 correctly?</p> <p>16 A. You did read that correctly.</p> <p>17 Q. So the authors of the paper that you've cited</p> <p>18 as one of the five papers that finds dose-response by</p> <p>19 measuring lifetime of cumulative use says the exact</p> <p>20 opposite; correct?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 THE WITNESS: If I may take just a</p> <p>23 moment. I want to find the part of this paper that</p> <p>24 supported the statement that I made in my report.</p> <p>25 MR. JAMES: Sure. Let's go off the</p>

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<p>1 record.</p> <p>2 THE VIDEOGRAPHER: Going off record at</p> <p>3 5:14 p.m.</p> <p>4 (Off the record.)</p> <p>5 THE VIDEOGRAPHER: Back on record at</p> <p>6 5:15 p.m.</p> <p>7 THE WITNESS: Okay. On page 817, it</p> <p>8 reads (as read):</p> <p>9 "Although a significant increase</p> <p>10 in risk with an increasing number</p> <p>11 of genital powder applications was</p> <p>12 found for non-mucinous epithelial</p> <p>13 ovarian cancer when non-users were</p> <p>14 included in the analysis."</p> <p>15 And it then goes on (as read):</p> <p>16 "Note trend in cumulative use was</p> <p>17 evident in analyses restricted to</p> <p>18 ever-users of genital powders."</p> <p>19 And so, again, my -- the statement that</p> <p>20 I had here, "a significant trend with increasing</p> <p>21 number of genital powder applications," they make the</p> <p>22 distinction of looking at the trend when you include</p> <p>23 non-users, and that's a pretty standard thing to do in</p> <p>24 epidemiology. It's -- you look -- can look as</p> <p>25 non-users as your reference group and then assess a</p>	<p>1 questions, Dr. Moorman.</p> <p>2 MR. JAMES: Michelle, is it fine if</p> <p>3 I have some time to review my notes while the others</p> <p>4 are asking questions and then come back?</p> <p>5 MS. PARFITT: Sure.</p> <p>6 MR. JAMES: Is that okay with you?</p> <p>7 MS. PARFITT: That's fine. Sure.</p> <p>8 MS. FOSTER: Can we go off and I'll</p> <p>9 switch.</p> <p>10 THE VIDEOGRAPHER: Going off the record</p> <p>11 at 5:18 p.m.</p> <p>12 (Off the record.)</p> <p>13 THE VIDEOGRAPHER: Back on record at</p> <p>14 5:20 p.m.</p> <p>15 CROSS-EXAMINATION BY COUNSEL FOR THE DEFENDANT</p> <p>16 IMERYS TALC AMERICA, INC.</p> <p>17 BY MS. FOSTER:</p> <p>18 Q. Good evening, Dr. Moorman. We met a long</p> <p>19 time ago this morning. My name is Jennifer Foster.</p> <p>20 I represent one of the Defendants in this action,</p> <p>21 Imerys Talc America, Inc. Do you understand that?</p> <p>22 A. Yes, I do.</p> <p>23 Q. And before you got involved in this</p> <p>24 litigation, did you know who Imerys Talc America, Inc.</p> <p>25 was?</p>
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<p>1 trend.</p> <p>2 I know what they say here, but I -- but</p> <p>3 I think that what I stated in my report is accurate,</p> <p>4 that they did find that a significant trend. So</p> <p>5 I don't think that I'm misstating what -- the data in</p> <p>6 the paper.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. So the results that are reported by the</p> <p>9 authors in the abstract you disagree with; correct?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 BY MR. JAMES:</p> <p>12 Q. The statements in the abstract pertaining to</p> <p>13 dose-response, do you disagree with those statements?</p> <p>14 A. What they say is "among genital powder</p> <p>15 users." And so the statement that they make is</p> <p>16 accurate, but I think that they are citing data</p> <p>17 that -- it's one way to look at the data, but I think</p> <p>18 that considering the non-users in their test for trend</p> <p>19 is also a very well-accepted way to do that, to do a</p> <p>20 test for trend.</p> <p>21 And so I think that both -- they reported</p> <p>22 one aspect of their analysis, and I reported what</p> <p>23 I think accurately reflects another aspect of their</p> <p>24 analysis.</p> <p>25 Q. Okay. I am getting close to the end of my</p>	<p>1 A. No, I did not.</p> <p>2 Q. Had you ever heard of them before?</p> <p>3 A. No.</p> <p>4 Q. And do you have an understanding of who they</p> <p>5 are now that you've become involved in the litigation?</p> <p>6 A. I do.</p> <p>7 Q. And you understand that Imerys mines and</p> <p>8 supplies talc to Johnson & Johnson for use in some of</p> <p>9 its talcum powder products?</p> <p>10 A. That is my understanding, yes.</p> <p>11 Q. Do you understand that Imerys does not sell</p> <p>12 talcum powder products directly to consumers?</p> <p>13 A. That was my understanding, yes.</p> <p>14 Q. And based on some testimony earlier today</p> <p>15 about the basis of your opinions being grounded in</p> <p>16 epidemiology studies about talcum powder products, am</p> <p>17 I correct that you wouldn't have any personal</p> <p>18 knowledge with respect to the composition of the talc</p> <p>19 that Imerys mines and supplies to Johnson & Johnson?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: No, I would not have that</p> <p>22 personal knowledge.</p> <p>23 BY MS. FOSTER:</p> <p>24 Q. And you have no opinions about any talc</p> <p>25 mining practices that Imerys employs; correct?</p>

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<p>1 A. I know nothing about their mining practices.</p> <p>2 Q. And you have no opinions about Imerys's</p> <p>3 compliance with any applicable standards or</p> <p>4 specifications regarding the mining of talc; correct?</p> <p>5 A. I do not know anything about that.</p> <p>6 Q. And I'm going to be hopping around a lot</p> <p>7 because Mr. James covered a lot of ground, so just</p> <p>8 bear with me. If I go somewhere and you don't know</p> <p>9 what I'm talking about, please just tell me you don't</p> <p>10 know what I'm talking about --</p> <p>11 A. Okay.</p> <p>12 Q. -- and I'll rephrase so that we can get on</p> <p>13 the same page.</p> <p>14 One of the first things you talked about</p> <p>15 this morning when you were talking to Mr. James is</p> <p>16 that you have entered a period I think you called</p> <p>17 preretirement transition. Do I have that right?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And do you have a retirement date in</p> <p>20 mind?</p> <p>21 A. That's still somewhat being discussed with my</p> <p>22 husband.</p> <p>23 Q. Okay. So you don't have a set "I'm going to</p> <p>24 retire in a year," for example?</p> <p>25 A. The exact date is not defined yet.</p>	<p>1 A. Yes, that is.</p> <p>2 Q. And is that a study that's designed to</p> <p>3 collect new data from study participants, or is that</p> <p>4 going to be an evaluation of data that you already</p> <p>5 have collected from other studies?</p> <p>6 A. It is a consortium that is planning to</p> <p>7 analyze data that have already been collected. It</p> <p>8 involves -- I believe it is a total of seven studies;</p> <p>9 some case-control, some cohort studies.</p> <p>10 Q. And -- were you finished? I'm sorry.</p> <p>11 A. Go ahead.</p> <p>12 Q. And how were the studies selected to be</p> <p>13 included in that consortium?</p> <p>14 A. It was -- the purpose of that was to try to</p> <p>15 put more data together, especially related to women of</p> <p>16 African ancestry. So they're all US studies, so</p> <p>17 African American. Recognizing that the AACES study,</p> <p>18 with about 600 cases, we still have some issues with</p> <p>19 statistical power. So we contacted -- Dr. Schildkraut</p> <p>20 is the PI on this study as well.</p> <p>21 And so studies that had a reasonable number</p> <p>22 of African American study participants, they were</p> <p>23 contacted to see if they were interested in</p> <p>24 participating in such a study.</p> <p>25 And so it includes studies such as the Black</p>
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<p>1 Q. And when you do retire, are you still going</p> <p>2 to have any involvement with what you've defined as</p> <p>3 the AACES study, the African American Cancer</p> <p>4 Epidemiology Study?</p> <p>5 A. That is still to be determined as well.</p> <p>6 Q. And am I correct that that study is still</p> <p>7 ongoing?</p> <p>8 A. The funding for that study ended -- I think</p> <p>9 it was 2015/2016. I don't recall the exact date. And</p> <p>10 so we have not collected any data for that study since</p> <p>11 that time.</p> <p>12 We have continued to do analysis of data</p> <p>13 that we have collected, and we are also trying to</p> <p>14 secure funding to continue data collection with that</p> <p>15 study.</p> <p>16 Q. That was going to be my question. Who have</p> <p>17 you made that request to for additional funding?</p> <p>18 A. The grant application was submitted to</p> <p>19 National Cancer Institute.</p> <p>20 Q. And that's who funded the original research;</p> <p>21 correct?</p> <p>22 A. That is correct.</p> <p>23 Q. And you also mentioned a publication that is</p> <p>24 in draft form regarding something called the OCWAA</p> <p>25 Consortium; is that correct?</p>	<p>1 Women's Health Study Cohort, that's out of Boston</p> <p>2 University; the Multiethnic Cohort, which is out of</p> <p>3 California; the Southern Community Cohort Study; the</p> <p>4 Women's Health Initiative; as well as a Los Angeles</p> <p>5 case-control study and a case-control study out of</p> <p>6 Chicago, in addition to the AACES study.</p> <p>7 I think that that's most of them.</p> <p>8 Q. Okay. Are you involved in any current</p> <p>9 research where the intent is to collect new data for</p> <p>10 evaluation of risk factors for ovarian cancer?</p> <p>11 A. Other than what I described to you, that we</p> <p>12 hope to -- that we are applying for funding to</p> <p>13 continue the AACES study, I'm not currently doing any</p> <p>14 data collection related to ovarian cancers.</p> <p>15 Q. Are the coauthors and coinvestigators that</p> <p>16 you worked with on the AACES and the North Carolina</p> <p>17 Ovarian Cancer Study aware of your involvement in the</p> <p>18 talcum powder litigation?</p> <p>19 A. Some of them are. I -- you know, as --</p> <p>20 I have disclosed it on one publication, and if they've</p> <p>21 read it, they are aware. I've discussed it with some</p> <p>22 of them but not all of them. You know, I haven't had</p> <p>23 a conversation, per se, with all of them.</p> <p>24 Q. And you mentioned earlier, with respect to</p> <p>25 some of the new publications that are in draft form</p>

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<p>1 that are currently in the peer review process, that 2 they have talc as a -- as a confounding factor under 3 investigation; correct? 4 A. I think -- I'm going to reread your -- 5 Q. I can rephrase it. 6 I think when you were talking earlier about 7 the studies that you have in draft, the question was 8 whether or not you had any publications that, you 9 know, mentioned talc. And I thought your testimony 10 was that talc was listed as a possible confounding 11 factor in some of the studies that were in draft form. 12 Is that correct? 13 A. Right. I mentioned that specifically in 14 relation to the infertility and ovarian cancer paper 15 that is in draft form, it's -- talc is considered as a 16 confounder there. 17 In regard to the description of the OCWAA 18 study, that paper, we are listing it as one of the 19 factors that we are likely to evaluate as a risk 20 factor for ovarian cancer. 21 Q. Okay. And my question is have you ever 22 included asbestos as a risk factor under investigation 23 in your epidemiology studies? 24 A. If I am not mistaken, I think that we had a 25 question on the AACES questionnaire that we asked if</p>	<p>1 did you have a particular paper in -- in mind? 2 BY MS. FOSTER: 3 Q. Not with 20 minutes left, no. 4 A. I'm sorry. I just -- you know, you're asking 5 me what did they mean, and I'm not even sure which 6 paper might have described something as a weak 7 positive association, and I'm not sure who would have 8 used that terminology or what was going through their 9 mind when they chose those words. 10 Q. I assume there are standard epidemiology 11 textbooks that you use in your field; correct? 12 A. Yes. 13 Q. Okay. And what are some of your go-to 14 epidemiology textbooks? 15 A. Let's see. Ken Rothman's Modern Epidemiology 16 is -- different editions of it have been around since 17 I was in school 30 years ago. I still refer to that. 18 When I have taught the physician assistant 19 students, the textbook that we use, which is a little 20 bit lower-level textbook, was going to us. Those are 21 probably my go-to ones. 22 Q. Okay. Do any of the standard epidemiology 23 textbooks use terms like "weak," "modest," "strong," 24 to describe associations? 25 A. I -- I imagine that in the textbooks, they</p>
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<p>1 women had ever been -- ever had a job where they were 2 exposed to asbestos, and I don't know that we have 3 analyzed that data yet. 4 Q. Okay. And you had some discussion with 5 Mr. James earlier today about different types of 6 terminology that might be used to describe 7 associations in the epidemiology literature. 8 Do you recall that? 9 A. Yes. 10 Q. And you were talking about weak associations, 11 modest associations, strong associations. Do you 12 remember that general discussion? 13 A. Yes. 14 Q. Now, as an epidemiologist, how would you 15 define a weak positive association? 16 A. As we have said before, there is no absolute 17 cut-point what's a weak association, what's a modest, 18 what's a moderate association. I -- I can't put a 19 number on that. I don't think any epidemiologist 20 could. 21 Q. In papers that you've authored that have used 22 the words "weak positive association," what do the 23 authors mean by that? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: I'm -- I'm not -- if --</p>	<p>1 might use that. But the point that I have been trying 2 to make is that there is no numerical value to go 3 along with those descriptors. 4 Q. All right. Switching topics, I want to talk 5 a little bit about some of the things that you 6 reviewed before you came and gave your deposition 7 today. 8 Now, you confirmed earlier that you reviewed 9 the reports of some of the other Plaintiffs' experts 10 in this case; correct? 11 A. Yes. 12 Q. And you reviewed those all between the time 13 that you finished your report and when you came here 14 to testify; correct? 15 A. That is correct. 16 Q. And those were all provided to you by 17 Plaintiffs' counsel; correct? 18 A. That is correct. 19 Q. And how did you choose which of the 22 expert 20 reports that you were going to sit down and read? 21 A. I knew which of the ones that were more of 22 the epidemiology-focused ones. And because that is my 23 area of expertise, those were the ones that I went to 24 first. 25 Also, some of it was, you know, some of the</p>

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<p>1 names that I recognized: David Kessler, former chair 2 of the -- former head of the FDA; Daniel 3 Clarke-Pearson, who is a gynecologic oncologist who 4 was formerly at Duke. He's now at UNC. 5 Q. Do you know Dr. Clarke-Pearson? 6 A. Only by reputation. 7 Q. You haven't talked to him about your opinions 8 in this litigation? 9 A. No, I have not. 10 Q. And you haven't talked to any other 11 Plaintiffs' expert about your opinions in this 12 litigation? 13 A. No, I have not. 14 Q. In reviewing those reports, did you work 15 under the assumption that the authors of those reports 16 had employed generally accepted methodologies in 17 forming their conclusions? 18 A. I -- I assumed that they had. You know, some 19 of the experts, they are names that I know, even if 20 I don't know the individual personally. You knows, 21 Dr. Siemiatycki, Dr. McTiernan, these are very 22 well-known epidemiologists. And so my assumption is 23 that they use generally accepted methodologies. 24 Q. I noticed on the 25 additional-materials-provided list -- I think it was</p>	<p>1 2016, and then updated it to make sure that my report 2 reflected the current literature. 3 Q. Did you do any kind of Bradford Hill analysis 4 of the claimed association between talcum powder usage 5 and ovarian cancer before you were retained as an 6 expert in the talcum powder litigation? 7 A. Doing -- considering the talcum powder -- or 8 considering the Bradford Hill criteria, this is 9 something that we do in our work all the time. It's 10 probably not as formalized as what was done here. 11 As you're aware, I was a coauthor, but I was 12 not the lead author on the AACES study of talc and 13 ovarian cancer. And in regard to the North Carolina 14 Ovarian Cancer Study, that was not the major focus of 15 the -- those papers that reported on talc and -- that 16 reported on talc as a risk factor. 17 So have I done the Bradford Hill criteria? 18 Certainly not in the detail that I have done for the 19 report that I prepared. 20 Q. And when you were -- when Mr. James asked you 21 about the NCI PDQ -- and you all looked at that as an 22 exhibit to the deposition. 23 Do you recall that earlier today? 24 A. Yes, I do. 25 Q. And one of the things that you mentioned is</p>
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<p>1 marked as Exhibit 8 earlier. It's a document that 2 I believe you said counsel had prepared, and it has 3 the expert reports on it. It also has a couple of 4 deposition transcripts on it from Dr. Plunkett and 5 Dr. Singh. 6 Did you review either of those before you 7 came and testified today? 8 A. Dr. Plunkett and Dr. Singh, S-I-N-G-H? 9 Q. Yes. 10 A. I don't believe that I read Dr. Plunkett's 11 deposition. I did read a fair bit of Dr. Singh's 12 deposition. 13 Q. When did you do that? 14 A. Probably a week or so ago. 15 Q. Do you have any intention of reading the rest 16 of the reports that Plaintiffs' counsel sent to you 17 after you're closed here today? 18 A. I think that it is possible that I will read 19 some of them, time permitting. 20 Q. You testified about a literature search that 21 you conducted on talcum powder and ovarian cancer. 22 When did you first conduct that search? 23 A. I believe that probably the first time I did 24 that search was not long after I was contacted about 25 possible involvement in this. So probably summer of</p>	<p>1 you see some kind of inconsistency in the way that NCI 2 evaluates data as to whether there is adequate 3 evidence of association or inadequate evidence of 4 association and specifically used the example of the 5 way that that they evaluated the breastfeeding data. 6 Do you remember that? 7 A. Right. What I -- I think the point that 8 I was trying to make when I was asked about that is 9 that the NCI PDQ, they do not describe their 10 methodology. So we're kind of left at what method did 11 they use to evaluate the data? Did they do a complete 12 systematic review, or was it -- was it something less 13 than a complete systematic review? 14 And my point is that, from the information 15 provided, we don't know what methods they used. 16 Q. Have you ever tried to communicate with any 17 of the editorial board members who write the NCI PDQ? 18 A. No, I have not. 19 Q. And you haven't submitted your report to 20 IARC; correct? 21 A. My -- 22 Q. Your expert report. You haven't submitted a 23 copy of your expert report to IARC for their 24 consideration; correct? 25 A. No, I have not.</p>

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<p style="text-align: right;">Page 294</p> <p>1 Q. Being conscious of the fact that we have</p> <p>2 limited time left, I'm going to -- okay. One last</p> <p>3 question.</p> <p>4 In terms of the expert report that you</p> <p>5 provided in the MDL litigation that we've been talking</p> <p>6 about all day today, are all of the opinions that you</p> <p>7 intend to give in this litigation contained within</p> <p>8 that report?</p> <p>9 A. I believe they are, yes.</p> <p>10 MS. FOSTER: I don't have anything else</p> <p>11 for you. So I'm going to pass you on to my colleague</p> <p>12 here. Thank you very much.</p> <p>13 THE WITNESS: Okay.</p> <p>14 CROSS-EXAMINATION BY COUNSEL FOR THE DEFENDANTS</p> <p>15 PERSONAL CARE PRODUCTS COUNCIL</p> <p>16 BY MS. APPEL:</p> <p>17 Q. Hi, Dr. Moorman. You can you hear me okay?</p> <p>18 A. I can, yes.</p> <p>19 Q. And just as a reminder from this morning,</p> <p>20 I am Renée Appel, and I represent Personal Care</p> <p>21 Products Council. And I just have a handful of</p> <p>22 questions to follow up on.</p> <p>23 When did you first form your opinion in your</p> <p>24 expert report that talcum powder products can cause</p> <p>25 ovarian cancer?</p>	<p style="text-align: right;">Page 296</p> <p>1 referring to talcum powder products?</p> <p>2 A. Yes, because all of the literature is -- the</p> <p>3 epidemiologic literature is based on talcum powder</p> <p>4 products, whatever the women reported that they used.</p> <p>5 Q. So is it correct, Dr. Moorman, that you had</p> <p>6 not formed an opinion as to whether pure talc is a</p> <p>7 risk factor for forming ovarian cancer?</p> <p>8 MS. PARFITT: Objection.</p> <p>9 THE WITNESS: Again, my opinion is</p> <p>10 based on the product that women have used, and my</p> <p>11 understanding is that all of the products, they have</p> <p>12 other constituents in them. So they may contain, you</p> <p>13 know, as we have discussed previously, fragrances, for</p> <p>14 example. We have also talked about that there are</p> <p>15 other -- there's evidence to suggest other</p> <p>16 constituents, such as asbestos or possibly heavy</p> <p>17 metals.</p> <p>18 BY MS. APPEL:</p> <p>19 Q. And as to those constituents, would you defer</p> <p>20 to other experts to opine on them, based on the</p> <p>21 examples you just provided, fragrances or heavy</p> <p>22 metals?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 THE WITNESS: You're asking me defer to</p> <p>25 other estimates to opine on them in what sense? Opine</p>
<p style="text-align: right;">Page 295</p> <p>1 A. I think that we have talked about this, that</p> <p>2 the literature on talc and ovarian cancer has been</p> <p>3 accruing since 1982, and to say at what point I formed</p> <p>4 my opinion that it causes ovarian cancer, I can't</p> <p>5 pinpoint that date.</p> <p>6 I can say that I have considered talc as a</p> <p>7 risk factor for ovarian cancer for quite some time.</p> <p>8 Just over my career, it just seems like it has been an</p> <p>9 accumulating volume of evidence.</p> <p>10 Q. Did you hold that opinion before you were</p> <p>11 retained as an expert in the talc litigation dating</p> <p>12 back to the Ingham case?</p> <p>13 A. I think that, yes, I did.</p> <p>14 Q. But, sitting here today, you can't recall a</p> <p>15 specific year or point in time in which you formed</p> <p>16 that opinion?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 THE WITNESS: I think that I've</p> <p>19 answered that. I can't pinpoint at what point that</p> <p>20 I concluded it was a risk factor for ovarian cancer.</p> <p>21 It's been something that I've considered a risk factor</p> <p>22 for ovarian cancer for quite -- quite a number of</p> <p>23 years.</p> <p>24 BY MS. APPEL:</p> <p>25 Q. And when you refer to "it," Doctor, are you</p>	<p style="text-align: right;">Page 297</p> <p>1 on them in what sense?</p> <p>2 BY MS. APPEL:</p> <p>3 Q. Sure. Would you defer to other experts to</p> <p>4 opine on whether those particular constituents in</p> <p>5 isolation are a risk factor for ovarian cancer?</p> <p>6 MS. PARFITT: Objection. Form. Asked</p> <p>7 and answered.</p> <p>8 THE WITNESS: Okay. Those particular</p> <p>9 constituents in isolation are a risk factor for</p> <p>10 ovarian cancer.</p> <p>11 I think that we have discussed this</p> <p>12 previously today, that what is the evidence about, for</p> <p>13 example, the heavy metals in isolation in ovarian</p> <p>14 cancer and limited to -- limited epidemiologic data in</p> <p>15 that regard.</p> <p>16 So I don't know that I'm deferring to other</p> <p>17 experts, but, as I phrased it earlier today, I --</p> <p>18 the -- whether or not these substances are in talc</p> <p>19 products, it adds to the biologic plausibility, but</p> <p>20 the epidemiologic data is based on the talc products.</p> <p>21 That's what the women were exposed to.</p> <p>22 BY MS. APPEL:</p> <p>23 Q. Okay. So in forming your opinion, you are</p> <p>24 assuming that those constituents that you've</p> <p>25 mentioned -- heavy metals, asbestos -- that they are</p>

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<p>1 in the talc powder product that you've rendered an 2 opinion about today? 3 MS. PARFITT: Objection. Misstates her 4 earlier opinions. 5 You might want to read that. 6 THE WITNESS: I -- I am not making, 7 really, any assumptions that these are in the 8 products. My -- you know, my focus on the 9 epidemiologic data is based on the use of the talc 10 products, whatever is contained in them. 11 BY MS. APPEL: 12 Q. In your report on page 30, you've indicated 13 that -- second paragraph, I'm reading from. And I'll 14 give you a moment to turn to it. (As read): 15 "For an association like talc and 16 ovarian cancer, the dose that is 17 most relevant is the amount of 18 talc that actually reaches the 19 fallopian tubes and ovaries." 20 Did I read that correctly? 21 A. Yes, you did. 22 Q. There is, in fact, though, no dose that has 23 been determined that actually reaches the fallopian 24 tubes and the ovaries in any of the studies that 25 you've relied upon; correct?</p>	<p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: I think that the sentence 3 that followed the one that you're reading is that, for 4 all the pragmatic reasons, we rely on the measures of 5 external application as a surrogate of the level of 6 exposure. There's no way that we could measure what 7 dose of talc reached the ovaries or the fallopian 8 tubes for something that women might have applied over 9 20, 30, 40 years of their lives. 10 BY MS. APPEL: 11 Q. Earlier today, you had discussed the 12 hierarchy of scientific evidence. 13 Do you recall that discussion? 14 A. I don't think that I used that terminology, 15 but I think that -- in talking about the 16 meta-analyses, yes. Yes. 17 Q. In terms of that hierarchy, that you 18 understand that I'm referring to based on that prior 19 discussion, where do cohort studies fall in comparison 20 to case-control studies? 21 MS. PARFITT: Objection. Asked and 22 answered. 23 THE WITNESS: Okay. If you have a 24 cohort study that was able to determine exposure 25 completely and accurately, and follow women for a</p>
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<p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: Let's see. 3 BY MS. APPEL: 4 Q. I can rephrase if you don't understand. 5 A. If you wouldn't mind, please. 6 Q. Absolutely. 7 In the studies that you've relied upon in 8 forming your opinion, none of those studies have 9 determined a particular dose of talc that actually 10 reaches the fallopian tubes and ovaries; correct? 11 MS. PARFITT: Objection. 12 THE WITNESS: Okay. So if we are 13 talking about the epidemiologic studies, there -- no, 14 of course, they did not measure what dose of talc 15 reached the ovaries and fallopian tubes. That would 16 not be feasible to do for -- reflecting the many, many 17 years of use, and also it would be completely 18 unfeasible to do something like that in an 19 epidemiologic study. 20 BY MS. APPEL: 21 Q. But you maintain the opinion that a 22 determination of that amount -- the amount being what 23 talc reaches the fallopian tubes and ovaries -- is 24 important to making a determination about an 25 association between talc and ovarian cancer; correct?</p>	<p>1 sufficient period of time, I think most people would 2 consider that a -- generally a stronger design than a 3 case-control study. 4 But, as I have indicated in my report, you 5 can't rely just on what is the stronger study design, 6 in general. You look -- have to look at the strengths 7 and limitations of the individual studies. 8 Cohort studies have some strengths; they 9 have some notable weaknesses. And I've described 10 those weaknesses several times over the course of 11 today. And I also acknowledge that case-control 12 studies have some weaknesses, but they also have 13 noticeable strengths too. 14 BY MS. APPEL: 15 Q. Is it accurate, Dr. Moorman, that, when you 16 were previously discussing meta-analyses and where 17 that falls on the hierarchy, you were envisioning a 18 pyramid graphic? Is that correct? 19 A. I have -- yes, I have seen graphics that 20 depict it like that. 21 Q. And in those particular graphics, where is 22 cohort studies listed in comparison to case-control 23 studies? 24 MS. PARFITT: Objection. 25 THE WITNESS: As I have said, that in</p>

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<p>1 that pyramid, it is -- typically, the cohort study is</p> <p>2 ranked as a stronger study design. But, again, I</p> <p>3 cannot emphasize strongly enough that you have to</p> <p>4 consider strengths and weaknesses of individual.</p> <p>5 BY MS. APPEL:</p> <p>6 Q. And, Dr. Moorman, have you considered</p> <p>7 publishing your expert report or the findings that you</p> <p>8 arrived at in your expert report?</p> <p>9 A. I have considered it. I have not actually</p> <p>10 done anything to translate it into a manuscript.</p> <p>11 MS. APPEL: Okay. Thank you,</p> <p>12 Dr. Moorman. That concludes my questions.</p> <p>13 THE WITNESS: Okay.</p> <p>14 MR. JAMES: I think there's about eight</p> <p>15 minutes. Off the record.</p> <p>16 THE VIDEOGRAPHER: Going off the record</p> <p>17 at 5:50 p.m.</p> <p>18 (Discussion off the record.)</p> <p>19 THE VIDEOGRAPHER: Back on record at</p> <p>20 5:51 p.m.</p> <p>21 FURTHER EXAMINATION BY COUNSEL FOR THE</p> <p>22 JOHNSON & JOHNSON DEFENDANTS</p> <p>23 BY MR. JAMES:</p> <p>24 Q. Dr. Moorman, in regard to your general cause</p> <p>25 opinion, do you hold the opinion that the evidence is</p>	<p>1 is sufficient to conclude that inhaled talcum powder</p> <p>2 can cause ovarian cancer?</p> <p>3 A. I do not think that there are epidemiologic</p> <p>4 studies that have actually looked at inhaled talcum</p> <p>5 powder in relation to ovarian cancer.</p> <p>6 Q. And so is your answer that -- let me just ask</p> <p>7 this again.</p> <p>8 Do you believe there's sufficient evidence</p> <p>9 upon which you can conclude that inhaled talc powder</p> <p>10 causes ovarian cancer?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: I think that I answered</p> <p>13 that when I said that I don't think that there are</p> <p>14 epidemiologic studies that have looked at that. So</p> <p>15 I can't say that there is sufficient evidence.</p> <p>16 BY MR. JAMES:</p> <p>17 Q. Dr. Moorman, are you generally aware that, in</p> <p>18 the African-American population, there is a lower</p> <p>19 incidence of ovarian cancer?</p> <p>20 A. Yes.</p> <p>21 Q. And you have -- have you also seen in the</p> <p>22 literature that there is at least some discussion in</p> <p>23 the literature that the prevalence of talcum powder</p> <p>24 used in the African-American populations may be</p> <p>25 higher?</p>
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<p>1 sufficient to support a general cause opinion for all</p> <p>2 subtypes of ovarian cancer or do you distinguish among</p> <p>3 the subtypes?</p> <p>4 A. Okay. The majority of the studies looked at</p> <p>5 epithelial ovarian cancer as a whole. Some of the</p> <p>6 studies did look at subtypes. As we are aware, the</p> <p>7 serous subtype is the vast majority, probably about</p> <p>8 60 -- maybe "vast majority" is overstating it. But</p> <p>9 serous subtypes are roughly 60 percent of ovarian</p> <p>10 cancer cases. And so the studies that looked at the</p> <p>11 subtypes tended to focus on that.</p> <p>12 The other subtypes -- the mucinous, the</p> <p>13 clear cell, and the other subtypes -- they are a much</p> <p>14 smaller percentage of epithelial ovarian cancer. And</p> <p>15 so there's really not adequate data to make a</p> <p>16 conclusion about these subtypes.</p> <p>17 Q. With regard to inhalation, which you touch</p> <p>18 upon in your report, do you hold the opinion that</p> <p>19 inhalation of talcum powder products can cause ovarian</p> <p>20 cancer?</p> <p>21 A. I have stated that that is a possible route</p> <p>22 of exposure to the ovaries. The epidemiologic studies</p> <p>23 have not specifically addressed the risk associated</p> <p>24 with inhalation only of talcum powder products.</p> <p>25 Q. So is there evidence upon which you believe</p>	<p>1 A. Yes.</p> <p>2 Q. If both of those things are true, can you</p> <p>3 provide us an explanation as to why -- why that would</p> <p>4 be the case?</p> <p>5 A. There are many causes of ovarian cancer. And</p> <p>6 some of the risk factors are more common in</p> <p>7 African-American women; some are less common.</p> <p>8 So when you consider the whole spectrum of</p> <p>9 risk factors, you know, breastfeeding, pregnancy, oral</p> <p>10 contraceptive use, to pinpoint one factor like talc</p> <p>11 that is used more frequently in African Americans and</p> <p>12 then say that that conflicts with the lower incidence</p> <p>13 of ovarian cancer that we see in African-American</p> <p>14 women, it doesn't take into account the full spectrum</p> <p>15 of risk factors.</p> <p>16 Q. With regard to the Health Canada assessment</p> <p>17 that we discussed much earlier today, do you</p> <p>18 understand that that assessment is in draft form</p> <p>19 currently?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: My understanding is that</p> <p>22 the scientific assessment they did is complete and</p> <p>23 that they are -- that there is a period of comment</p> <p>24 that -- so, I'm sorry, I want to make sure...</p> <p>25</p>

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<p>1 BY MR. JAMES: 2 Q. Do you understand that right now that 3 assessment is currently in the process of a comment 4 period? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: My understanding is the 7 assessment of the risk that they did, that is 8 complete, and then they are assessing -- or it is in a 9 comment period. And I think that, you know, 10 potentially, if there were some serious concerns 11 raised, they might revisit the risk assessment that 12 they did. But my understanding is what they published 13 is their -- that they felt like the risk assessment 14 was complete. 15 BY MR. JAMES: 16 Q. And to be very quick here, I understand that 17 one of the materials provided to you in the additional 18 materials list was the Taher paper; correct? 19 A. Yes. 20 Q. And do you understand that the Taher paper is 21 one of the items discussed in the Health Canada 22 assessment? 23 A. Yes. 24 Q. And do you understand the Taher paper's 25 conclusion is consistent with the IARC's conclusion of</p>	<p>1 A. Yes, I -- 2 MS. PARFITT: Is the question is that 3 what it says? 4 BY MR. JAMES: 5 Q. That is the question. 6 We had a discussion earlier today about 7 possible cause; correct? 8 A. Yes. 9 MS. PARFITT: Objection. 10 BY MR. JAMES: 11 Q. And, Dr. Moorman, with respect to the 12 Bradford Hill analysis -- 13 MS. PARFITT: Can we stop for a minute? 14 Are you going to tell us when we're off and 15 when we're done? 16 THE VIDEOGRAPHER: Just one minute. 17 MS. PARFITT: Thank you. Oh, that's 18 good. 19 BY MR. JAMES: 20 Q. With respect to your Bradford Hill 21 analysis -- and this should be my last question -- 22 A. Okay. 23 Q. -- you will agree with me that in order to 24 reach a causal conclusion, you must rely on items 25 other than the cohorts, case controls, and</p>
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<p>1 possible cause? 2 MS. PARFITT: Objection. Form. 3 Misstates the evidence. 4 THE WITNESS: If you have the Taher 5 paper -- again, just recalling exactly what they 6 stated, I -- too many papers to remember all the 7 detail. 8 BY MR. JAMES: 9 Q. When is the last time you reviewed the Taher 10 paper? 11 A. I would say probably a week or two ago. 12 MR. JAMES: So if Michelle doesn't cut 13 me off, I will hand you a copy of it. I'm going to 14 mark it as Exhibit 31. 15 (Exhibit No. 31 was marked for identification.) 16 BY MR. JAMES: 17 Q. I'll hand you two copies. 18 Okay. And, Dr. Moorman, again, because I'm 19 running out of time, I'll direct you to the precise 20 portion of the article that founds my question. It's 21 on page 49, and it's in the conclusion section of the 22 paper. 23 And you see in the last sentence -- in the 24 last sentence, they report that the data indicates 25 "possible cause of ovarian cancer"?</p>	<p>1 meta-analyses of the epidemiologic literature; 2 correct? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: The -- some of the 5 Bradford Hill aspects which I think I discussed in my 6 report were the biological plausibility, and so I did 7 rely on literature other than the epidemiologic 8 literature. 9 BY MR. JAMES: 10 Q. And those are necessary as part of your 11 methodology to reach a causal conclusion; correct? 12 MS. PARFITT: Objection. Form. 13 THE WITNESS: They are a consideration. 14 When you do a Bradford Hill analysis, of course you 15 take into account the biological plausibility and the 16 data that may come from cancer biology studies, animal 17 studies, and so on. So yes, it should be considered. 18 MR. JAMES: Okay. Dr. Moorman, thank 19 you for your time. 20 THE WITNESS: Okay. 21 MS. PARFITT: Can we go off the record, 22 please. 23 THE VIDEOGRAPHER: Going off the record 24 at 6:01 p.m. 25 (Recess taken from 6:01 p.m. to 6:14 p.m.)</p>

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<p>1 THE VIDEOGRAPHER: Back on record at 2 6:15 p.m. 3 CROSS-EXAMINATION BY COUNSEL FOR THE PLAINTIFF 4 BY MS. PARFITT: 5 Q. Dr. Moorman, good evening. 6 A. Good evening. 7 Q. I just have a few questions to follow up with 8 counsel for J&J and then for PCPC. 9 Dr. Moorman, you were asked not too long ago 10 by Mr. James a question with regard to your general 11 causation opinions as they relate to does talc -- do 12 talcum powder products cause ovarian cancer. 13 Do you remember that discussion? 14 A. Yes, I do. 15 Q. All right. And I believe the question dealt 16 with subtypes of epithelial ovarian cancer. 17 Do you remember that? 18 A. Yes. 19 Q. All right. And I believe your testimony was 20 that there's really not adequate data to make a 21 conclusion about the subtypes. 22 Did you mean, when you said that, that 23 there's not adequate data to make a conclusion about 24 these other subtypes, that that was because the 25 non-serous subtypes were relatively rare?</p>	<p>1 of the opinion of Health Canada vis-à-vis exposure to 2 talcum powder products and ovarian cancer? 3 A. My -- my understanding is that Health Canada 4 indicated that talcum powder products can cause 5 ovarian cancer. 6 Q. Mr. James showed you a study, the Taher 7 study. 8 A. Yes. 9 Q. And you had an opportunity to review the 10 Taher study as well; correct? 11 A. Yes. 12 Q. Is the Taher study a -- one of the pieces of 13 evidence that you looked at in your review of the 14 Health Canada assessment? 15 A. One of -- it's one of the pieces of evidence, 16 but not the sole body of evidence that they 17 considered. 18 Q. Okay. And is the Taher study also considered 19 a meta-analysis? 20 A. Yes. 21 Q. Okay. For purposes of rendering your 22 opinions in this case, that talcum powder products can 23 cause ovarian cancer, you have shared with the ladies 24 and gentlemen of the jury that you have reviewed 25 multiple meta-analyses; correct?</p>
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<p>1 A. Yes, but the bulk of the literature is 2 addressing epithelial ovarian cancer, which includes 3 all of the subtypes. 4 Q. All right. So that the ladies and gentlemen 5 are clear as to what your opinion is, is it your 6 opinion that talcum powder products can cause -- or 7 exposure -- let me strike that. 8 Is it your opinion that exposure to talcum 9 powder products can cause ovarian cancer? Is that 10 your opinion? 11 A. That is my opinion. 12 Q. All right. And does that include all types 13 of epithelial ovarian cancer? 14 A. That -- yes. The data are based -- are 15 largely based on all types of epithelial ovarian 16 cancer. Yes. 17 Q. You were questioned a little earlier, and 18 briefly, about the Health Canada assessment. Do you 19 recall those discussions? 20 A. Yes. 21 Q. Okay. And have you had an opportunity to 22 review the recommendations of Health Canada? 23 A. I have, yes. 24 Q. All right. Based upon your review of the 25 Health Canada assessment, what is your understanding</p>	<p>1 A. That is correct. 2 Q. And I believe you spent time today talking 3 with us with regard to the various meta-analyses that 4 you've looked at, examined, and assessed; correct? 5 A. That is correct. 6 Q. Okay. Based upon the totality of the 7 meta-analyses that you have reviewed, what is your 8 opinion with regard to whether or not they demonstrate 9 that talcum powder products can cause ovarian cancer? 10 A. I think that the meta-analyses show 11 consistent conclusions of a 25 to 30 percent increased 12 risk for ovarian cancer; and that coupled with the 13 other criteria that I considered -- the biological 14 plausibility and the various other Bradford Hill 15 criteria -- that I came to the conclusion that talc is 16 a cause of ovarian cancer. 17 Q. Dr. Moorman, is it fair to say that the 18 method -- method of review and your methodology and 19 the analysis that you performed, for purposes of the 20 preparation of your report and the opinions that you 21 shared today, is the type of methodology and the type 22 of process that is generally accepted in your 23 scientific community of epidemiologists? 24 MS. FOSTER: Objection to form. 25 THE WITNESS: I think that the methods</p>

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<p>1 that I used are what I do routinely in my work as an</p> <p>2 epidemiologist and that is routinely done when we</p> <p>3 conduct systematic reviews.</p> <p>4 BY MS. PARFITT:</p> <p>5 Q. You were questioned numerous times today with</p> <p>6 regard to the IARC review of talcum powder products</p> <p>7 and ovarian cancer. Do you recall those discussions?</p> <p>8 A. Yes, I do.</p> <p>9 Q. The IARC committee put out a monograph in</p> <p>10 2010. Is that your understanding?</p> <p>11 A. That is my understanding, yes.</p> <p>12 Q. Do you have any knowledge as to when the IARC</p> <p>13 committee met to make their findings as it pertained</p> <p>14 to the role of talcum powder products in ovarian</p> <p>15 cancer?</p> <p>16 A. I don't recall the exact date, but I believe</p> <p>17 that it was quite a bit earlier than that. I'm not</p> <p>18 sure of the exact date.</p> <p>19 Q. Okay. But it preceded the monograph that</p> <p>20 came out in 2010?</p> <p>21 A. Yes.</p> <p>22 MS. PARFITT: Dr. Moorman, I have no</p> <p>23 further questions. Thank you very much. I appreciate</p> <p>24 it. A long day.</p> <p>25 MR. JAMES: Dr. Moorman, just a handful</p>	<p>1 A. The most pronounced difference that we are</p> <p>2 aware of is that smoking seems to be more strongly</p> <p>3 associated with mucinous ovarian cancer than with</p> <p>4 other subtypes.</p> <p>5 But in most -- for most other risk factors,</p> <p>6 there -- the risk factors seem to be pretty consistent</p> <p>7 across the subtypes.</p> <p>8 Q. Are you aware that many clinicians consider</p> <p>9 the various subtypes of ovarian cancer to be different</p> <p>10 diseases?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 THE WITNESS: I think that clinicians</p> <p>13 recognize that they -- there are differences. Again,</p> <p>14 going to pathologists, they can distinguish between</p> <p>15 them.</p> <p>16 But in terms of how they treat them, it's</p> <p>17 my -- I'm not aware of any real difference in how they</p> <p>18 would treat the different subtypes of ovarian cancer.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. And other than smoking, which is the factor</p> <p>21 that you just mentioned, can you think of any other</p> <p>22 risk factors that have a different impact on a</p> <p>23 specific subtype of ovarian cancer as opposed to</p> <p>24 another subtype?</p> <p>25 A. That is the only one that comes to mind.</p>
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<p>1 more questions. Okay?</p> <p>2 THE VIDEOGRAPHER: Mr. James.</p> <p>3 MR. JAMES: Oh, of course.</p> <p>4 Can we go off just for one second?</p> <p>5 How long did Ms. Parfitt go?</p> <p>6 THE VIDEOGRAPHER: Going off record at</p> <p>7 6:22 p.m.</p> <p>8 (Discussion off the record.)</p> <p>9 THE VIDEOGRAPHER: Back on record at</p> <p>10 6:23 p.m.</p> <p>11 FURTHER EXAMINATION BY COUNSEL FOR THE</p> <p>12 JOHNSON & JOHNSON DEFENDANTS</p> <p>13 BY MR. JAMES:</p> <p>14 Q. Dr. Moorman, since the IARC published its</p> <p>15 monograph in 2010, we have had the publication of</p> <p>16 additional cohort data on the talc ovarian cancer</p> <p>17 association; correct?</p> <p>18 A. Correct.</p> <p>19 Q. With regard to the subtypes issue, do you</p> <p>20 believe that different subtypes of ovarian cancer have</p> <p>21 different risk profiles?</p> <p>22 MS. PARFITT: Objection. Form.</p> <p>23 You can answer.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. And I'm talking about in general.</p>	<p>1 MR. JAMES: That's all I have. Thank</p> <p>2 you again for your time.</p> <p>3 THE WITNESS: Okay.</p> <p>4 MS. PARFITT: Thank you.</p> <p>5 THE VIDEOGRAPHER: This concludes the</p> <p>6 deposition of Dr. Patricia Moorman. The time going</p> <p>7 off record is 6:25 p.m.</p> <p>8 (Whereupon, at 6:25 p.m., the deposition ceased.</p> <p>9 Signature was reserved.)</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2 I, PATRICIA G. MOORMAN, M.S.P.H., PH.D., do</p> <p>3 hereby acknowledge that I have read and examined the</p> <p>4 foregoing testimony, and the same is a true, correct,</p> <p>5 and complete transcription of the testimony given by me,</p> <p>6 and any corrections appear on the attached errata sheet</p> <p>7 signed by me.</p> <p>8</p> <p>9 _____</p> <p>10 (DATE) (SIGNATURE)</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 STATE OF NORTH CAROLINA)</p> <p>2) CERTIFICATE</p> <p>3 COUNTY OF ORANGE)</p> <p>4 I, Sophie Brock, Court Reporter and Notary Public,</p> <p>5 the officer before whom the foregoing proceeding was</p> <p>6 conducted, do hereby certify that the witness(es) whose</p> <p>7 testimony appears in the foregoing proceeding were duly</p> <p>8 sworn by me; that the testimony of said witness(es) were</p> <p>9 taken by me to the best of my ability and thereafter</p> <p>10 transcribed under my supervision; and that the foregoing</p> <p>11 pages, inclusive, constitute a true and accurate</p> <p>12 transcription of the testimony of the witness(es).</p> <p>13 I do further certify that I am neither counsel for,</p> <p>14 related to, nor employed by any of the parties to this</p> <p>15 action, and further, that I am not a relative or</p> <p>16 employee of any attorney or counsel employed by the</p> <p>17 parties thereof, nor financially or otherwise interested</p> <p>18 in the outcome of said action.</p> <p>19 This, the 26th day of January, 2019.</p> <p>20</p> <p>21</p> <p>22 _____</p> <p>23 Sophie Brock, RDR, CRR</p> <p>24 Notary Number: 200834000001</p> <p>25</p>																																																																																				
<p>Page 319</p> <p>1 ERRATA</p> <p>2 CASE NAME: TALCUM POWDER LITIGATION MDL NO. 2738</p> <p>3 WITNESS NAME: PATRICIA G. MOORMAN, M.S.P.H., PH.D.</p> <p>4 CASE NUMBER: 16-2738 (FLW)(LHG)</p> <table border="1"><thead><tr><th>5</th><th>PAGE LINE</th><th>READS</th><th>SHOULD READ</th></tr></thead><tbody><tr><td>6</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>7</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>8</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>9</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>10</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>11</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>12</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>13</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>14</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>15</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>16</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>17</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>18</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>19</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>20</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>21</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>22</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>23</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>24</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>25</td><td>_____</td><td>_____</td><td>_____</td></tr></tbody></table>	5	PAGE LINE	READS	SHOULD READ	6	_____	_____	_____	7	_____	_____	_____	8	_____	_____	_____	9	_____	_____	_____	10	_____	_____	_____	11	_____	_____	_____	12	_____	_____	_____	13	_____	_____	_____	14	_____	_____	_____	15	_____	_____	_____	16	_____	_____	_____	17	_____	_____	_____	18	_____	_____	_____	19	_____	_____	_____	20	_____	_____	_____	21	_____	_____	_____	22	_____	_____	_____	23	_____	_____	_____	24	_____	_____	_____	25	_____	_____	_____	
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Exhibit 86

Jack Siemiatycki, Ph.D.

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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IN RE JOHNSON & JOHNSON) MDL No.
TALCUM POWDER PRODUCTS) 16-2738 (FLW)(LHG)
MARKETING SALES PRACTICES,)
AND PRODUCTS LIABILITY)
LITIGATION)
)
THIS DOCUMENT RELATES TO)
ALL CASES)

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VIDEOTAPED DEPOSITION OF
JACK SIEMIATYCKI, Ph.D.
MONTREAL, CANADA
THURSDAY, JANUARY 31, 2019
9:49 A.M.

Reported by: Leslie A. Todd

Jack Siemiatycki, Ph.D.

<p style="text-align: right;">Page 2</p> <p>1 Deposition of JACK SIEMIATYCKI, Ph.D., held at 2 the offices of: 3 4 5 CHUM Research Center 6 Montreal, Canada 7 8 9 10 11 12 Pursuant to notice, before Leslie Anne Todd, 13 Court Reporter and Notary Public in and for the 14 District of Columbia, who officiated in 15 administering the oath to the witness. 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES (Continued): 2 3 RICHARD GOLOMB, ESQUIRE 4 GOLOMB & HONIK, LLP 5 1835 Market Street 6 Suite 2900 7 Philadelphia, Pennsylvania 19103 8 (215) 278-4449 9 rgolomb@golombhonik.com 10 ON BEHALF OF THE JOHNSON & JOHNSON DEFENDANTS: 11 KIMBERLY OLVEY BRANSCOME, ESQUIRE 12 KIRKLAND & ELLIS LLP 13 333 South Hope Street 14 Los Angeles, California 90071 15 (213) 680-8370 16 kimberly.branscome@kirkland.com 17 JESSICA BRENNAN, ESQUIRE 18 DRINKER BIDDLE & REATH LLP 19 600 Campus Drive 20 Florham Park, New Jersey 07932 21 (973) 540-1000 22 jessica.brennan@dbr.com 23 24 25</p>
<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S 2 3 ON BEHALF OF THE PLAINTIFFS: 4 CHRISTOPHER V. TISI, ESQUIRE 5 LEVIN PAPANTONIO, LLP 6 316 South Baylen Street 7 Pensacola, Florida 32502 8 (850) 435-7184 9 ctisi@levinlaw.com 10 MICHELLE A. PARFITT, ESQUIRE 11 ASHCRAFT & GEREL, LLP 12 4900 Seminary Road, Suite 650 13 Alexandria, Virginia 22311 14 (703) 997-1774 15 MParfitt@ashcraftlaw.com 16 ALASTAIR J.M. FINDEIS, ESQUIRE 17 NAPOLI SHKOLNIK, PLLC 18 360 Lexington Avenue 19 11th Floor 20 New York, New York 10017 21 (212) 397-1000 22 23 24 25</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES (Continued): 2 3 ON BEHALF OF THE PCPC: 4 RENEE APPEL, ESQUIRE (Telephonically) 5 SEYFARTH SHAW LLP 6 975 F Street, N.W. 7 Washington, DC 20004 8 (202) 828-5371 9 rappel@seyfarth.com 10 ON BEHALF OF THE IMERY'S DEFENDANTS: 11 MICHAEL R. KLATT, ESQUIRE 12 GORDON & REES SCULLY MANSUKHANI, LLP 13 816 Congress Avenue, Suite 1510 14 Austin, Texas 78701 15 (512) 391-0183 16 mklatt@grsm.com 17 ON BEHALF OF PTI: 18 CAROLINE M. TINSLEY, ESQUIRE (for PTI) 19 TUCKER ELLIS, LLP 20 100 South 4th Street, Suite 600 21 St. Louis, Missouri 63102 22 (314) 571-4965 23 caroline.tinsley@tuckerellis.com 24 ALSO PRESENT: 25 FABIO DEFELICE (Videographer)</p>

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Jack Siemiatycki, Ph.D.

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5	By Ms. Parfitt	290	5	Risk Factors For Cancer in the	
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9	SIEMIATYCKI DEPOSITION EXHIBITS	PAGE	9	Confounding Bias Related to	
10	No. 1 Notice of Oral and Videotaped		10	Smoking, Ethnic Group, and	
11	Deposition of Jack Siemiatycki		11	Socioeconomic Status in Estimates	
12	and Duces Tecum (not attached)	15	12	of the Associations Between	
13	No. 2 Plaintiffs' Steering Committee's		13	Occupation and Cancer," Journal of	
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2	(Attached to transcript)		2	-----	
3	SIEMIATYCKI DEPOSITION EXHIBITS	PAGE	3	THE VIDEOGRAPHER: Good morning. We're	
4	No. 7 JS EpiTech Inc. bill for		4	now on the record. My name is Fabio DeFelice.	
5	Professional Services, August 9 -		5	I'm the videographer for Golkow Litigation	
6	November 16, 2018	46	6	Services. Today's date is January 31st of 2019.	
7	No. 8 JS EpiTech Inc. bill for		7	The time is 9:49 a.m.	
8	Professional Services, July 1 -		8	This video deposition is being held at	
9	August 2, 2018	48	9	the CHUM Research Center in Montreal, Canada, in	
10	No. 9 Report of Jack Siemiatycki dated		10	the matter In Re: Johnson & Johnson Talcum Powder	
11	October 4th, 2016 (not attached)	58	11	Products in the United States District Court for	
12	No. 10 Expert Report of Jack Siemiatycki		12	the Eastern District of New Jersey. The case	
13	Msc, PhDn Talcum Powder Use and		13	number is 16-2738.	
14	Ovarian Cancer (not attached)	61	14	The deponent is Jack Siemiatycki, Ph.D.	
15	No. 11 Expert Report of Jack Siemiatycki		15	The counsel will be noted on the	
16	MSc, PhD on Talcum Powder Use and		16	stenographic record. The court reporter is Leslie	
17	Ovarian Cancer (with handwritten		17	Todd, and will now swear in the witness.	
18	notations)	110	18	JACK SIEMIATYCKI, Ph.D.,	
19	No. 12 Berge 2012 report (not attached)	194	19	and having been first duly sworn,	
20	No. 13 Schildkraut report (not attached)	214	20	was examined and testified as follows:	
21	No. 14 Anita Koushik information from		21	DIRECT EXAMINATION	
22	Environepi website	278	22	BY MS. BRANSCOME:	
23	No. 15 Pages from Environepi website		23	Q Good morning, Dr. Siemiatycki.	
24	discussing Group Research Topics	285	24	A Good morning. Nice to meet you.	
25			25	Q We met just before the deposition	

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Jack Siemiatycki, Ph.D.

<p style="text-align: right;">Page 10</p> <p>1 started, but my name is Kimberly Branscome, and I 2 am here to ask you questions today on behalf of 3 Johnson & Johnson. 4 Is that all right? 5 A Thank you. Yes. 6 Q All right. We are taking your 7 deposition today in the case of In Re: Johnson & 8 Johnson Talc Litigation, MDL. 9 Is it your understanding that you have 10 been designated as a testifying expert in that 11 case? 12 A Yes. 13 Q When were you first contacted about 14 serving as an expert witness in the MDL 15 litigation? 16 A I believe it was in the spring or summer 17 of 2018, but I'm not positive about that. 18 Q Who contacted you? 19 A Ms. Parfitt. 20 Q Have you communicated with any other 21 lawyers regarding your work on the talc MDL? 22 A I've had a couple of meetings with 23 Ms. Parfitt and her colleagues that she works 24 with. 25 Q Can you identify the individuals with</p>	<p style="text-align: right;">Page 12</p> <p>1 anyone else present at those meetings? 2 A No. 3 Q You didn't have anyone from your team, 4 for example, present? 5 A No. 6 MS. PARFITT: Objection. Form. 7 BY MS. BRANSCOME: 8 Q What did you do to prepare for your 9 deposition today? 10 A Do you mean from the beginning of my 11 involvement in the MDL case back last summer or do 12 you mean just in the last few days? 13 Q Let's take it more broadly. 14 What have you done to develop your 15 opinions in this case, and then specifically to 16 prepare for your deposition? 17 A I reviewed -- I rereviewed the 18 literature about talc and ovarian cancer, 19 scientific literature. I evaluated it, I wrote a 20 report about it. And in the last few days, I went 21 over all of the -- not all, but a lot of the 22 material that I had gone through initially and 23 just clarified for myself, looked for any issues 24 that I had missed the first time around, things 25 like that.</p>
<p style="text-align: right;">Page 11</p> <p>1 whom you have met in addition to Ms. Parfitt? 2 A Yes, there are two, and they are here 3 present. Chris Tisi and Alastair -- 4 MR. FINDEIS: Findeis. 5 THE WITNESS: Say that again. 6 MS. PARFITT: Findeis. 7 THE WITNESS: And that's -- thank you. 8 BY MS. BRANSCOME: 9 Q How many meetings have you had to 10 prepare for your expert opinions in the MDL? 11 A One yesterday and one about a month -- 12 about three weeks ago. 13 Q Where did those meetings take place? 14 A Here. 15 Q And by "here," do you mean in Montreal? 16 A In Montreal, yes. 17 Q How long did each meeting last? 18 A Yesterday's was about four, five hours 19 maybe. Four or five hours. And the earlier one, 20 I guess all told, about ten hours maybe. 21 Q Did the ten-hour meeting take place over 22 one day? 23 A Over two days. 24 Q In addition to the attorneys that you 25 just identified for the record and yourself, was</p>	<p style="text-align: right;">Page 13</p> <p>1 Q As part of your review of materials in 2 preparation for today, did you identify anything 3 in your review that changed the opinions that you 4 have offered in the expert report in the MDL? 5 A No. Those opinions remain valid. 6 Q When you say that you rereviewed the 7 scientific literature in preparation for the 8 development of your opinions in the MDL, what did 9 you mean by "rereviewed"? 10 A Well, I had reviewed -- I've reviewed 11 evidence around talc and ovarian cancer on a few 12 different occasions. The first time was in 2006 13 when I was on an international review committee on 14 the topic. Then in 2015, '16, '17, in preparation 15 for another litigation regarding talc and ovarian 16 cancer. Then in the summer/fall of 2018, in 17 preparation for writing a report that was 18 submitted for this case. And then in the last 19 week or two, roughly speaking, I went over all of 20 that. So I refer to that as a rereview. 21 Q Have you ever discussed your deposition 22 with any of -- of the other experts designated by 23 the plaintiffs in the MDL? 24 A No, I haven't. 25 Q Have you discussed your expert opinions</p>

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<p>1 with any of the other experts designated by the 2 plaintiffs in the MDL? 3 A No, I haven't. 4 Q Are you aware of the list of experts 5 that have been designated by the plaintiffs in the 6 MDL? 7 A I'm aware of at least some of them. I'm 8 not sure if I'm aware of all of them, but I'm 9 aware of some of them. 10 Q Who specifically are you aware of? 11 A Singh, McTiernan, Laura Plunkett. And 12 there are a few more, and I could look it up. 13 Q I'd like to start by just marking the 14 deposition notice for your deposition as 15 Exhibit 1. 16 Dr. Siemiatycki, you will see two large 17 binders over there in front of you. This will be 18 tab 1. 19 So I'd like -- 20 A I see it. 21 Q I'd like to mark for identification 22 the document behind tab 1, which is 23 Dr. Siemiatycki's deposition notice as Exhibit 1 24 to this deposition. 25 MS. PARFITT: Do you want to give me --</p>	<p>1 your deposition that were submitted by plaintiffs' 2 counsel in the MDL. And this one we actually will 3 need to mark a copy, because it's not in your 4 binder. 5 (Exhibit No. 2 was marked for 6 identification.) 7 MS. BRANSCOME: Do you have an extra 8 copy, Michelle? 9 MS. PARFITT: I do. Not a worry. I got 10 it. 11 BY MS. BRANSCOME: 12 Q Dr. Siemiatycki, have you ever seen the 13 document that has been marked as Exhibit 2, which 14 is the plaintiffs' general objections to your 15 deposition notice? 16 A I'm not sure. 17 MS. PARFITT: I will represent for the 18 record that's not been provided to 19 Dr. Siemiatycki. 20 BY MS. BRANSCOME: 21 Q All right. So if you could, 22 Dr. Siemiatycki, did you bring any materials with 23 you today to the deposition? 24 A Yes, I brought a lot of documents, just 25 in case.</p>
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<p>1 Do you want me to just mark them? Will 2 that help you, instead of reaching across the 3 table? It's up to you. I can put the stickers on 4 it. 5 (A discussion was held off the record.) 6 (Exhibit No. 1 was marked for 7 identification.) 8 BY MS. BRANSCOME: 9 Q Dr. Siemiatycki, are you familiar with 10 the document that we have just marked as 11 deposition Exhibit 1? 12 A I've seen something like this. I'm -- 13 not reading through it, I'm not sure if it's 14 exactly the same document that I have seen before, 15 but I guess this is kind of the standard format of 16 notice that is sent to experts ahead of time. So 17 I've seen -- I've seen that. 18 Q Do you understand that what has been 19 marked as Exhibit 1, which is the notice for your 20 deposition, requests that you bring certain 21 documents with you to this deposition? 22 A Yes. 23 Q All right. And just for completeness 24 and at the request of plaintiffs' counsel, I will 25 also mark as Exhibit 2 the general objections to</p>	<p>1 Q Can you identify for me, and we can 2 start with a general category first, if that's 3 helpful, the materials that you brought with you 4 today to your deposition? 5 A Well, I brought my report. I brought an 6 addendum to my report, which I think has been 7 provided to you. 8 MS. PARFITT: Yes, that was the table. 9 THE WITNESS: It's a long -- it's a set 10 of -- 11 MS. PARFITT: I have a copy of that if 12 you wish to have it marked. Do you want it -- if 13 you give me a number, I will put it on this one. 14 BY MS. BRANSCOME: 15 Q Let's see. Yeah, let's go ahead and 16 mark the addendum to your expert report as 17 Exhibit 3. 18 (Exhibit No. 3 was marked for 19 identification.) 20 BY MS. BRANSCOME: 21 Q Dr. Siemiatycki, could you just confirm 22 for the record that what we have marked as 23 Exhibit 3 is in fact the complete addendum to your 24 MDL expert report? 25 A I -- I believe it is. I believe it is.</p>

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<p>1 Q What else did you bring with you today?</p> <p>2 A I'm not sure if this is the right time</p> <p>3 to mention it, but there were a couple of -- in</p> <p>4 the past few days I picked up a couple of typos in</p> <p>5 my report, and I've hand scribbled them on my</p> <p>6 copy, and I can tell you about those very quickly,</p> <p>7 but I'm not sure if this is now the right time for</p> <p>8 this or later.</p> <p>9 Q I will ask you about any corrections</p> <p>10 that you have, but it is good to know that the</p> <p>11 report you brought with you has some handwriting</p> <p>12 on it, so we will make sure to mark that copy.</p> <p>13 A Okay.</p> <p>14 Q What else did you bring with you today?</p> <p>15 A I brought -- well, I brought three</p> <p>16 binders of material that were part of the -- the</p> <p>17 references to my report.</p> <p>18 MS. PARFITT: And if I may, I provided</p> <p>19 counsel in advance of the deposition a thumb drive</p> <p>20 that contains all of Dr. Siemiatycki's report but</p> <p>21 also the references related to that report.</p> <p>22 THE WITNESS: I brought a couple of</p> <p>23 binders -- well, more than a couple. It looks</p> <p>24 like five binders of different documents that I</p> <p>25 thought might be useful in answering questions</p>	<p>1 Agency for Research on Cancer, of the meeting held</p> <p>2 in Lyon in 2006. The book was published in 2010,</p> <p>3 and it contains an evaluation of talc</p> <p>4 carcinogenicity as of 2006.</p> <p>5 The next one is a textbook of</p> <p>6 epidemiology that is probably considered the most</p> <p>7 respected one in the field at this point, authored</p> <p>8 by Rothman, T -- R-O-T-H-M-A-N, Greenland,</p> <p>9 G-R-E-E-N-L-A-N-D, and Lash, L-A-S-H.</p> <p>10 MR. KLATT: Dr. Siemiatycki, is there a</p> <p>11 particular edition or is there --</p> <p>12 THE WITNESS: Oh, yeah. Yeah, this one</p> <p>13 is third edition. Thank you.</p> <p>14 The fourth one is kind of a handbook</p> <p>15 called Dictionary of Epidemiology, edited by</p> <p>16 Porta, P-O-R-T-A, which is kind of a very basic</p> <p>17 book of definitions.</p> <p>18 And the fifth one is called An</p> <p>19 Introduction to Meta-Analysis. The first author</p> <p>20 is Borenstein, B-O-R-E-N-S-T-E-I-N.</p> <p>21 BY MS. BRANSCOME:</p> <p>22 Q All right. Focusing first on the books</p> <p>23 that you brought with you, why did you bring with</p> <p>24 you a book about Risk Factors --</p> <p>25 A For cancer.</p>
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<p>1 that you might ask. So it was -- I was just</p> <p>2 speculating on the types of questions you might</p> <p>3 ask and brought documents that might help to</p> <p>4 answer or to support arguments or statements that</p> <p>5 I would make. I brought five --</p> <p>6 MS. PARFITT: You can get --</p> <p>7 THE WITNESS: -- which --</p> <p>8 MS. PARFITT: -- the texts --</p> <p>9 THE WITNESS: The textbooks. I brought</p> <p>10 five books with me, again in the same spirit that</p> <p>11 things might come up that it would be helpful to</p> <p>12 refer to material in these books. One -- should I</p> <p>13 tell you what they are?</p> <p>14 BY MS. BRANSCOME:</p> <p>15 Q If you would, please, identify each of</p> <p>16 the books --</p> <p>17 A Okay.</p> <p>18 Q -- for the record, and we will return to</p> <p>19 the eight binders that you just mentioned.</p> <p>20 A One is a book called Risk Factors for</p> <p>21 Cancer in the Workplace. And it's a book that I</p> <p>22 wrote 30 years ago about occupational causes of</p> <p>23 cancer.</p> <p>24 The other one -- the next one is the</p> <p>25 monograph of IARC, which is the International</p>	<p>1 Q -- for Cancer in the Workplace?</p> <p>2 A Because it has -- in that book I -- I</p> <p>3 described my research. I described the research</p> <p>4 findings from my projects in this area. I also</p> <p>5 described the process of conducting epidemiologic</p> <p>6 research and drawing inferences from epidemiologic</p> <p>7 data, and how -- what are the considerations that</p> <p>8 would be used in drawing inferences from</p> <p>9 epidemiologic data for cancer causation. And I</p> <p>10 thought this might come up during the day.</p> <p>11 Q Do the methodological principles that</p> <p>12 you outline in your book, Risk Factors for Cancer</p> <p>13 in the Workplace, are those still current in your</p> <p>14 view today?</p> <p>15 A Yes.</p> <p>16 Q And why specifically did you want to</p> <p>17 have this book available to you during your</p> <p>18 deposition?</p> <p>19 A In case any of the statements that I've</p> <p>20 made in my report about evaluating causation and</p> <p>21 how epidemiology is used for evaluating causation</p> <p>22 are challenged. And specifically, I was</p> <p>23 anticipating that there may be challenges to the</p> <p>24 fact that my approach to this question might be</p> <p>25 new and just sort of concocted in the context of</p>

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<p>1 the litigation, and I wanted to show that in my 2 own sort of intellectual history, these ideas have 3 been there forever but certainly for the last 30 4 years, and that these are commonly held views. 5 Q Are there specific chapters within the 6 book that you brought with you that you would 7 direct someone to to gain information about the 8 methodology that you applied in the MDL? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: I'm sorry. Could you 11 repeat the question? 12 BY MS. BRANSCOME: 13 Q Understanding that what you brought with 14 you -- 15 A Yes. 16 Q -- is a complete book -- 17 A Yes. 18 Q -- are there specific chapters that you 19 contend contain an explanation of the methodology 20 that is similar to what you have applied in your 21 analysis in the MDL? 22 MS. PARFITT: Objection. Form, broad. 23 THE WITNESS: So I would say there are 24 two chapters that have relevance to the issue at 25 hand. The last chapter contains a discussion of</p>	<p>1 A Yeah. 2 Q -- in the MDL? 3 A I -- yes, I -- I collected as much 4 information, data from different research studies 5 as possible. I evaluated those studies. I 6 ordered them according to the types of evidence 7 that they provide. I tried to synthesize the 8 evidence in particular in the basket of 9 epidemiologic research on the topic. And I 10 juxtaposed the information from epidemiologic 11 evidence with evidence derived from other domains 12 which are provided by other experts. And I made a 13 professional judgment about how all of that fits 14 with different ways of understanding the 15 relationship between perennial use of talc and the 16 risk of ovarian cancer. 17 Q Is the methodology that you just 18 described that you used in forming your opinions 19 in the MDL described in the textbook that you 20 brought with you about risk factors in the 21 workplace? 22 A It is implicit. It is implicit in the 23 work of epidemiologists, and it's implicit in the 24 way we synthesize information. So, in 25 epidemiologic practice, the role of -- there's no</p>
Page 23	Page 25
<p>1 causality and how to use epidemiology in the 2 process of determining causality. 3 The first -- the second chapter contains 4 information -- excuse me, I think it's the second 5 chapter -- contains information about different 6 epidemiologic research designs, and it's a 7 discussion of case-controlled studies, cohort 8 studies, and other types of epidemiologic designs 9 and their relative advantages and disadvantages. 10 BY MS. BRANSCOME: 11 Q Is there a description of the 12 methodology that you have applied in your analysis 13 in the MDL that is directly described in the book 14 that you just referenced? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: I'm not sure what you mean 17 by "directly," and I'm not sure what you mean by 18 "methodology." 19 BY MS. BRANSCOME: 20 Q Did you apply a specific methodology in 21 reaching your opinions here in the MDL? 22 A What do you mean by "a specific 23 methodology"? 24 Q Did you -- did you use a methodology in 25 forming your opinions --</p>	<p>1 cookbook recipe in how you start the day and 2 finish the day. You collect data. You use your 3 best judgment about how to synthesize and 4 integrate it. And I guess it comes under the 5 rubric of weight of evidence. You look at all of 6 the evidence, and you (weigh it according to your 7 professional judgment. 8 And most of the agencies that have any 9 policies or statements about synthesizing 10 information will talk about collecting 11 information, evaluating it, weighing it, and 12 making a judgment about it. 13 Q If someone were reviewing just your 14 report in the MDL, would they be able to replicate 15 the weight that you gave different pieces of 16 evidence that you considered? 17 A The synthesis of scientific information 18 is not an automated process. It can't be done by 19 a robot. And in every description of how such 20 evidence is synthesized and integrated, the final 21 step always involves professional judgment, and as 22 it should, because there are too many moving parts 23 in all of this to be able to, a priori, set up an 24 algorithm that allows you to automate and arrive 25 at some score that tells you, yes or no, this</p>

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<p>1 agent is dangerous or not dangerous or something 2 like that. 3 So in line with everything I've done in 4 my career, everything that I've been involved with 5 in international and national agencies, whether 6 it's USNCI or the World Health Organization or 7 other agencies, the process depends critically on 8 judgment of the people who are making the 9 decisions or who are making the evaluations. 10 Q Respectfully, Dr. Siemiatycki, that was 11 not my question. 12 My question was, could someone by 13 reviewing the report that you have provided in the 14 MDL replicate your analysis in the sense that they 15 would understand the weight that you gave to each 16 piece of evidence you considered? 17 A I think to a considerable extent I've 18 given fairly explicit information in the report on 19 all of the components of information that I used 20 and the relative weight, but -- not in a 21 quantitative way, but the relative importance that 22 I attribute to different parts of the evidence 23 package. 24 Q You did not do any type of scoring 25 system, for example, in considering the various</p>	<p>1 selected, when they were selected, when they were 2 followed up, how -- all of these things may have a 3 different score, and you may have a hundred 4 dimensions to evaluate on each study. And nobody 5 has come up with a -- a usable, useful, 6 replicatable method for integrating all of this. 7 There have been some attempts and there are some 8 scoring systems out there. The fact that there 9 are scoring -- that someone has published a 10 scoring system, and that even a committee has, 11 does not mean that it's valid. 12 But I -- my professional opinion, and 13 that of I think many other people -- because 14 typically studies are not scored in this way. 15 That's -- when people review evidence. Or if 16 they -- anyway, typically they are not, and my 17 feeling is that there is no valid way really of 18 doing it. 19 But the -- in order to sort of complete 20 the answer to I think what's behind your question 21 of why I didn't do such a thing in my report with 22 all of the studies is that I adopted early on -- I 23 made a decision early on to avoid excluding 24 studies from my analysis based on my opinion about 25 the quality of the study. This is a decision that</p>
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<p>1 underlying studies that you evaluated. Is that 2 fair? 3 A No -- no, I did not, because I don't 4 consider that a valid procedure. 5 Q Why is that not a valid procedure? 6 A Because I don't think epidemiologic 7 studies can be summarized in single-digit scores. 8 There are too many different aspects of a study, 9 and any attempt to do so, I think is flawed and -- 10 Q Why is the attempt to assigning a score, 11 single digit or otherwise, a flawed methodology? 12 A Because there are so many -- a study can 13 be good in one dimension, mediocre in a third, 14 excellent in a fourth, bad in a fifth, so-so in a 15 sixth, and so on. 16 There are so many dimensions of a study, 17 and each one of them can be rated. And that's -- 18 that is something that I do do. I evaluate 19 everything from participation rate to the 20 population in which the study was carried out, to 21 the way the questions were asked in the 22 questionnaire, to the way the information from the 23 questionnaire was -- was coded and categorized, to 24 the way the design of the -- whether its case 25 controlled or otherwise, how the subjects were</p>	<p>1 other meta-analyses have also made implicitly. I 2 don't know if they've made it explicitly, but 3 there are no studies that have -- as far as I 4 know, there are no meta-analyses that have 5 literally excluded studies on the basis of quality 6 or -- or done a systematic attempt to do this. 7 And I made a decision early on that if I 8 tried to -- if I went down the road of eliminating 9 some studies from my analysis, this would be 10 criticized as some form of cherry-picking, and in 11 an attempt to avoid that criticism, I decided I 12 would include all pieces of evidence, 13 notwithstanding my opinion of the overall quality 14 of the study. 15 Q Okay. Dr. Siemiatycki, that was a very 16 long answer, but I will try to unpack a few -- 17 A Yes. 18 Q -- portions of that. 19 So you would agree that in order for a 20 methodology to be valid, it has to be a process 21 that can be replicated? 22 MS. PARFITT: Objection. Form. 23 THE WITNESS: What do you mean by 24 "replicated"? You mean that someone else 25 following exactly the same steps and the -- making</p>

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<p>1 the same assumptions as the -- the person who did 2 the analysis would be able to end up with the same 3 statistical estimates at the end? Is that what 4 you mean? Or do you mean that they would make the 5 same judgments? 6 BY MS. BRANSCOME: 7 Q Well, Dr. Siemiatycki, you indicated one 8 of the reasons why you don't agree with using a 9 quantitative point system was that a methodology 10 had not been developed that was, I believe you 11 said, useful, usable and replicable. 12 What did you mean by the word 13 "replicable" when you used it in your own answer? 14 A Did I use the word "replicable" in that 15 sentence? Can I -- can I read that? (Peruses 16 monitor.) 17 I'm not sure what I had in mind with the 18 use -- the word -- yes, you can produce a 19 replicable system, but it doesn't mean that it's 20 valid. So useful and usable, yes. I don't think 21 that there is one that would capture, for 22 observational epidemiology, the -- all of the 23 components that are necessary really to tease out 24 good and/or bad studies. 25 BY MS. BRANSCOME:</p>	<p>1 giving to the pieces of evidence that he or she is 2 considering in reaching their ultimate conclusion. 3 Is that fair? 4 MS. PARFITT: Objection. Form. 5 THE WITNESS: It depends what you mean 6 by "weight." If you mean by "weight" a 7 quantitative number, then, no, that's not 8 necessary. 9 If you mean sort of a heuristic, 10 qualitative understanding of the relative 11 importance of different components of evidence, 12 then I would say yes. It's important to know what 13 played into a -- a reviewer's opinion. 14 BY MS. BRANSCOME: 15 Q You also indicated that you do in fact 16 rate studies. What did you mean by that? 17 A Sorry. Can we read back where I said 18 that? I -- (peruses monitor.) 19 I haven't found it, but I -- I think I 20 meant it as a synonym for evaluate. I think I 21 meant I evaluate different studies. 22 Q Okay. If I could direct your 23 attention -- 24 A Yes. 25 Q -- to pages -- page 19, lines 6</p>
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<p>1 Q My question to you, though, 2 Dr. Siemiatycki, is that, is it important for a 3 methodology to be replicable? 4 A It is important -- the most important is 5 for it to be valid. The replicability is an issue 6 that involves judgment. Different scientists may 7 have different judgments about the value of 8 different components of evidence. That diversity 9 of judgment is not a bad thing, and there's no 10 benefit to science in forcing everyone to have the 11 same judgment within some scoring system. 12 So science progresses from collection of 13 data and from different scientists evaluating the 14 data, and from the same information base different 15 scientists can make different judgments about it, 16 and in that sense, the final evaluations are not 17 necessarily replicable because different 18 scientists can make different judgments. 19 But they are understandable. You need 20 the different processes to be sufficiently 21 understandable that different readers and so on of 22 reports can understand how you came to the 23 conclusions. 24 Q And so it is important to be able to 25 understand what weight a particular scientist is</p>	<p>1 through 8. 2 A Of -- 19 of -- of what? 3 Q Of the transcript that's -- 4 A Okay. 5 Q -- in front of you, which understanding 6 is just a rough, but if you want to review your 7 answer. 8 A Sure. (Peruses document.) 9 Yes, here by "rated," I meant evaluated. 10 Q Did you rank the different pieces of 11 evidence that you considered in forming your 12 opinion with respect to talc and the risk of 13 ovarian cancer? 14 A I -- I've never done that in the 15 hundreds and hundreds of evaluations I've carried 16 out, nor in this one do I actually put a score on 17 different components of -- of a study. Yeah. 18 Q My question is slightly different, 19 Dr. Siemiatycki. 20 It's ranking them relative to each 21 other. So whether or not you're assigning a 22 specific quantitative number to the study, do you 23 evaluate this is, for instance, the most important 24 study and this is the least important study on a 25 particular topic?</p>

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<p style="text-align: right;">Page 34</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 THE WITNESS: You mean overall or in --</p> <p>3 in each dimension that the -- that a study is</p> <p>4 comprised of?</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q Did you do any type of ranking of that</p> <p>7 nature, be it in a subtopic or overall?</p> <p>8 A Not -- not explicitly, no.</p> <p>9 Q You mentioned at the -- at the end of</p> <p>10 your answer that you made a decision not to</p> <p>11 exclude studies because you would not want to face</p> <p>12 the criticism of cherry-picking; is that correct?</p> <p>13 A Yes, I said that.</p> <p>14 Q What is your understanding of the</p> <p>15 criticism of cherry-picking?</p> <p>16 A My understanding is that one would --</p> <p>17 one might look at a body of evidence, have a</p> <p>18 preconceived notion about the topic, the</p> <p>19 hypothesis under consideration, and use those</p> <p>20 studies that support that hypothesis and discard</p> <p>21 the other ones in some way.</p> <p>22 Q Is that good science, in your opinion?</p> <p>23 A No, that's not good science.</p> <p>24 Q Why not?</p> <p>25 A Because it doesn't produce an objective</p>	<p style="text-align: right;">Page 36</p> <p>1 conclusion.</p> <p>2 BY MS. BRANSCOME:</p> <p>3 Q When I asked you the question of whether</p> <p>4 or not the methodology you applied here in forming</p> <p>5 your opinion in the MDL is contained in the book</p> <p>6 that you wrote about Risk Factors for Cancer in</p> <p>7 the Workplace, you said it was implicit.</p> <p>8 Is that methodology explicitly described</p> <p>9 in that textbook or any of the other textbooks you</p> <p>10 brought with you today?</p> <p>11 A I'm not sure that the methodology -- you</p> <p>12 know, I think it -- the collection of data, the</p> <p>13 evaluation of data, the judgment about the</p> <p>14 collection of data is a part of the scientific</p> <p>15 method, and it is so engrained and implicit in</p> <p>16 epidemiology and in other sciences that you don't</p> <p>17 really need to -- and scientists don't write in</p> <p>18 their books or in their -- unless they're talking</p> <p>19 to first-year students -- talk about this. It's</p> <p>20 so elementary that those aspects are not really</p> <p>21 described. One goes further in describing</p> <p>22 specific methodologies that would pertain to the</p> <p>23 topic under consideration.</p> <p>24 Q Are there different ways to perform a</p> <p>25 meta-analysis?</p>
<p style="text-align: right;">Page 35</p> <p>1 portrait of reality.</p> <p>2 Q If a scientist were to selectively</p> <p>3 identify studies that were supportive of his or</p> <p>4 her preconceived notion, would you consider that</p> <p>5 analysis to be a valid one?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 THE WITNESS: Do you mean -- just -- I'm</p> <p>8 just trying to parse your question. You said if a</p> <p>9 scientist were to identify studies that were</p> <p>10 supportive, et cetera, but also that were in</p> <p>11 opposition or to exclude ones that are in</p> <p>12 opposition?</p> <p>13 BY MS. BRANSCOME:</p> <p>14 Q Fair enough.</p> <p>15 So referring back to the scenario that</p> <p>16 you have described as cherry- picking --</p> <p>17 A Yes.</p> <p>18 Q -- if a scientist were to engage in</p> <p>19 cherry-picking, would you consider the ultimate</p> <p>20 conclusion that that scientist reached with</p> <p>21 respect to causation or increased risk of an agent</p> <p>22 to be a valid one?</p> <p>23 A It should be suspect --</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: It would be a suspect</p>	<p style="text-align: right;">Page 37</p> <p>1 A Yes.</p> <p>2 Q Okay. Did the method that you chose in</p> <p>3 developing your meta-analysis, is that explicitly</p> <p>4 described in any of the materials you either</p> <p>5 brought here with you today or of which you are</p> <p>6 aware in the scientific community?</p> <p>7 A So it partly depends what you mean by "a</p> <p>8 meta-analysis." And in my lexicon, meta-analysis</p> <p>9 is a statistical procedure for summarizing a body</p> <p>10 of -- a set of results from individual studies.</p> <p>11 And that procedure is pretty standard -- has been</p> <p>12 pretty standard since the 1980s and 1990s, and</p> <p>13 there are some refinements since then.</p> <p>14 Sorry, I may have lost the thread of</p> <p>15 your question.</p> <p>16 Q If I were to try to look at a piece of</p> <p>17 scientific literature, be it in a book or an</p> <p>18 article, to find a published description of the</p> <p>19 method that you used to perform your meta-analysis</p> <p>20 in the MDL, where would I look?</p> <p>21 A The meta-analysis was conducted using a</p> <p>22 software that is well known, that is commercially</p> <p>23 available, and I think everyone would recognize</p> <p>24 the validity of the statistical procedures under</p> <p>25 those -- under that.</p>

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<p style="text-align: right;">Page 38</p> <p>1 If you're asking about which -- you 2 know, there are decisions to be made about which 3 studies to include, about which results from 4 studies to include, and all of that sort of thing, 5 which is not strictly part of the statistics of 6 meta-analysis, it's sort of the step before 7 meta-analysis, and that part is utterly unique to 8 each situation. 9 So if you're doing a meta-analysis of 10 clinical trials that have all been designed 11 basically in an identical way for an 12 antihypertensive medication, and whether the study 13 is done in Australia or California or Canada, the 14 design is pretty standard, and a lot of it can 15 be -- you can -- and you end up basically with a 16 single result from the study, what is the impact 17 on blood pressure -- the average impact on blood 18 pressure among people who use it who were given 19 the drug, the experimental group versus a 20 comparison group, et cetera, that is one type of 21 preparation for a meta-analysis. 22 If you're dealing with observational 23 epidemiology, as we are in the case of ovarian 24 cancer, and some of the particularities of the 25 literature in this domain, there are a lot of</p>	<p style="text-align: right;">Page 40</p> <p>1 clarify. 2 So the three -- the three binders that 3 you referred to as sort of this first set of 4 materials, are those all references that are 5 identified specifically in your report from the 6 MDL? 7 A Yes, I believe so. And just to be 8 clear, when I was sent this material from the 9 lawyers' office, it arrived in four binders. I'm 10 not sure if you received the same four binders. I 11 have re- -- I've taken some things out of there, 12 so I have three binders of those things. Just -- 13 I don't know if there's confusion just between the 14 three and four, but... 15 Q What did you remove from the set of 16 materials that you were provided by plaintiffs' 17 counsel? 18 A I removed the IARC reports, which I have 19 in books, so I didn't need to carry around 20 hundreds and hundreds of pages extra. 21 I removed some other -- there was 22 another report with, you know, thousands of -- 23 hundreds or -- at least of pages where I thought 24 the relevant material was in -- contained in about 25 20 pages. So I kept -- in material that I carry</p>
<p style="text-align: right;">Page 39</p> <p>1 decisions that need to be made in the run-up to 2 the meta-analysis. 3 Q So in the situation where you are 4 dealing with observational epidemiology, would it 5 be fair to say that you are applying unique 6 judgment in the selection of the studies that you 7 include in your meta-analysis and, more 8 specifically, what data from those studies you 9 include. 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: Any meta-analysis in this 12 area would absolutely need to apply professional 13 judgments to those things. 14 BY MS. BRANSCOME: 15 Q Okay. 16 A Mine included and every -- everyone 17 else's included. 18 Q All right. So, Dr. Siemiatycki, getting 19 back to the materials that you brought with you 20 today, you mentioned that you brought three 21 binders of scientific literature. Was that 22 correct? 23 A Three binders of the references to my 24 report. 25 Q Okay. So that's what I wanted to</p>	<p style="text-align: right;">Page 41</p> <p>1 around, I kept the 20 pages and put the rest away 2 in a box. 3 Q Do you remember which document that was? 4 A If you give me a minute, I'll try to 5 recreate that. 6 Q We can check that at the break if you 7 want -- 8 A Yeah. Sure, sure. 9 Q -- to identify that document. 10 So then you -- you spoke about an 11 additional five binders -- 12 A Yeah. 13 Q -- that you brought with you that 14 contain documents that might help you answer 15 questions during the deposition. 16 Can you describe the contents of those 17 five binders. I'm trying to avoid marking all of 18 these as exhibits. 19 A Yeah. Please. 20 Okay. Let me just reach down and look 21 at their covers. 22 Yeah, so one contains the recent 23 manuscript of a study by Taher, et al., a Canadian 24 meta-analysis of the issue, plus -- let me see if 25 there's anything else in there. I -- I think</p>

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<p>1 that's it. It's such a -- such a big report with</p> <p>2 all the appendices and so on, that it takes up a</p> <p>3 whole binder.</p> <p>4 Another one, a smaller one, contains the</p> <p>5 meta -- the main meta-analyses that have been done</p> <p>6 in this area, apart from the Taher one. So the</p> <p>7 Berge, Penninkilampi, a few other older ones,</p> <p>8 Langseth and some of the older ones.</p> <p>9 Q Are those materials that are in the set</p> <p>10 of meta-analysis, the second binder, if you will,</p> <p>11 are they replicated also in the other set of three</p> <p>12 binders that you brought with you?</p> <p>13 A Yes, they are.</p> <p>14 Q Okay.</p> <p>15 A Yes, they are.</p> <p>16 Sorry. There's -- there's another one</p> <p>17 in -- like that which contains all of the original</p> <p>18 epidemiology studies that I used or that were</p> <p>19 available to be used in the meta-analysis. And I</p> <p>20 had this binder in my previous -- in the previous</p> <p>21 case that I testified on, and I thought I -- I'd</p> <p>22 like to have one binder here just of the</p> <p>23 epidemiology studies because the thick binders,</p> <p>24 it's harder for me to find articles, so it would</p> <p>25 be easier for me to find them in this binder. So</p>	<p>1 identification.)</p> <p>2 BY MS. BRANSCOME:</p> <p>3 Q Now, Dr. Siemiatycki, with the exception</p> <p>4 of a copy of your report, which you previously</p> <p>5 testified has some handwritten annotations on it,</p> <p>6 do any of the other materials that you brought</p> <p>7 with you today have any notes, handwritten or</p> <p>8 typed, or highlighting or any other form of</p> <p>9 annotation?</p> <p>10 A Yes. The -- the epidemiology studies</p> <p>11 and probably the meta-analyses, the previous</p> <p>12 meta-analyses. I -- I tend to scribble notes when</p> <p>13 I'm reading an article on the side, so some of</p> <p>14 those may very well have scribbled notes on -- in</p> <p>15 the margins or things underlined.</p> <p>16 Q Dealing first with the binder of the</p> <p>17 original epidemiological studies that you said you</p> <p>18 had at a prior deposition, have you annotated that</p> <p>19 in any way since you brought that to another</p> <p>20 deposition?</p> <p>21 A Since today? Sorry.</p> <p>22 MS. BRANSCOME: Michelle, perhaps you</p> <p>23 could help me.</p> <p>24 MS. PARFITT: Sure. Yeah, absolutely.</p> <p>25 MS. BRANSCOME: Has that specific binder</p>
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<p>1 all of these are in the big binders.</p> <p>2 And there's another one with Health</p> <p>3 Canada weight of evidence guidelines. Also</p> <p>4 guidelines from a European agency on weight of</p> <p>5 evidence and evaluation. I think there might be</p> <p>6 something from FDA about that, and also some of</p> <p>7 the information regarding agency -- what agencies</p> <p>8 have put on their websites, if anything, about</p> <p>9 talc, which would include the National Cancer</p> <p>10 Institute and some other agencies.</p> <p>11 So these are mainly -- well, partly</p> <p>12 printouts from websites. Partly the Canadian Risk</p> <p>13 Management scope for talc published very recently</p> <p>14 from the Canadian Department of Health. And this</p> <p>15 sort of information. Not -- not all of those are</p> <p>16 in the thick binders.</p> <p>17 Q Are all of the documents in the binder</p> <p>18 that you are holding there, which I think is your</p> <p>19 fifth binder, are all of those documents</p> <p>20 identified within your report or in your reference</p> <p>21 materials?</p> <p>22 A No.</p> <p>23 Q I would like to mark that binder as</p> <p>24 Exhibit 4.</p> <p>25 (Exhibit No. 4 was marked for</p>	<p>1 been marked as an exhibit at a prior deposition?</p> <p>2 MS. PARFITT: Let me see which one.</p> <p>3 Ms. Branscome, I don't want to</p> <p>4 represent -- and I would tell you that these were</p> <p>5 all the studies that he's had over the course of</p> <p>6 the last few years. I can't imagine it wasn't</p> <p>7 asked for in prior depositions, but I can't -- I</p> <p>8 can't represent --</p> <p>9 MS. BRANSCOME: Okay.</p> <p>10 MS. PARFITT: -- one way or another. I</p> <p>11 really can't.</p> <p>12 MS. BRANSCOME: Let's go ahead. I would</p> <p>13 like to mark the binder --</p> <p>14 MS. PARFITT: I will tell you this --</p> <p>15 maybe I can. There are pink numbers, number 10,</p> <p>16 number 14, which suggest to me that they might</p> <p>17 have been referenced in a deposition at one point</p> <p>18 in time as an exhibit.</p> <p>19 THE WITNESS: Not -- some of them, but</p> <p>20 not all of them, have those numbers.</p> <p>21 MS. PARFITT: Okay.</p> <p>22 THE WITNESS: They also have numbers in</p> <p>23 the corner of my -- my team's personal filing</p> <p>24 system of articles, so things like that.</p> <p>25 MS. BRANSCOME: Out of an abundance of</p>

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<p>1 caution, we will mark the binder that has been 2 described as containing the original 3 epidemiological studies as Exhibit 5, and the 4 binder that contains the meta-analyses as 5 Exhibit 6. 6 (Exhibit Nos. 5 and 6 were marked 7 for identification.) 8 BY MS. BRANSCOME: 9 Q Did you bring anything else with you to 10 the deposition today? 11 A Cell phone, glasses, et cetera, but no. 12 Q I was provided before the deposition 13 began with a single piece of paper that I 14 understand to be a bill for professional services. 15 If we could mark a copy of that as 16 Exhibit 7. 17 MS. BRANSCOME: Michelle, I don't know 18 if you have an extra copy. 19 MS. PARFITT: I do. 20 (Exhibit No. 7 was marked for 21 identification.) 22 MS. PARFITT: I have additional copies 23 for counsel, if you would like. 24 MS. BRANSCOME: I think we passed one 25 around.</p>	<p>1 A Okay. 2 Q So why don't we mark as Exhibit 8 the 3 bill for professional services that covers the 4 month of July. 5 (Exhibit No. 8 was marked for 6 identification.) 7 MS. PARFITT: Sure. I don't have extras 8 of those. Does anyone have a clamp? If I could 9 have one of those? Thank you. 10 MR. TISI: Number 7, for the record, is 11 the one that goes to November. 12 MS. BRANSCOME: We'll -- we'll clear it 13 up. 14 MR. TISI: Thank you. 15 THE WITNESS: Got it. 16 BY MS. BRANSCOME: 17 Q So, Dr. Siemiatycki, you have two 18 exhibits in front of you there, an Exhibit 7 and 19 an Exhibit 8. 20 Do they both contain bills for 21 professional services for the work that you have 22 done in connection with this litigation? 23 A Yes, they do. 24 Q And what has been marked as Exhibit 7 25 covers a work period of August 9th through</p>
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<p>1 BY MS. BRANSCOME: 2 Q Dr. Siemiatycki, do you recognize the 3 document that's been placed in front of you that's 4 been marked as Exhibit 7? 5 A Yes, I do. 6 Q And could you describe for the record 7 what this document is. 8 A It's a bill for services that I sent to 9 Ms. Parfitt dated November 18, 2018, in which I 10 billed for work done between August and November 11 2018 on the MDL case. 12 Q Is it correct that this is a bill that 13 covers 56 hours that you billed in connection with 14 your work on this case in the month of July 15 through August 2nd, 2018? 16 A Sorry, do -- July? Is this the same -- 17 MS. PARFITT: August. I have August to 18 November. 19 THE WITNESS: Do you have a bill labeled 20 July? 21 MS. PARFITT: We have July to August, 22 and here's the August -- 23 BY MS. BRANSCOME: 24 Q Sorry, we had different pieces of paper, 25 Dr. Siemiatycki.</p>	<p>1 November 16th, 2018, during which you billed 136 2 hours; is that correct? 3 A That's correct. 4 Q And then Exhibit 8 covers the period of 5 time July 1st through August 2nd, 2018, over which 6 you billed 56 hours; is that correct? 7 A That's correct. 8 Q And you bill for your time at \$450 an 9 hour, correct? 10 A That's correct. 11 Q Do the two bills for professional 12 services that have been marked as Exhibits 7 and 8 13 contain any time for work done by others at your 14 direction? 15 A They contain work that has been done by 16 a couple of -- by one research assistant, and I 17 make an arrangement with her to reimburse her for 18 her time. So it's -- it's covered in these, yes. 19 Q Okay. And so how is your research 20 assistant's time billed to plaintiffs' counsel? 21 A It's not billed. I -- I adjust the 22 billable hours to reflect the time that she works 23 for me. 24 Q So if I was looking at Exhibit 7 and 25 Exhibit 8, how much in terms of hours of this</p>

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<p>1 reflects your personal time?</p> <p>2 A Between 95 percent and 98 percent,</p> <p>3 almost all of it.</p> <p>4 Q And do the two exhibits that you have in</p> <p>5 front of you there, Exhibit 7 and Exhibit 8, does</p> <p>6 that cover all of the work that you have done in</p> <p>7 connection with forming your opinions in this</p> <p>8 case, meaning the MDL?</p> <p>9 A In forming the opinions for the report,</p> <p>10 yes.</p> <p>11 Q These bills do not include time that you</p> <p>12 spent preparing for today's deposition, correct?</p> <p>13 A That's correct.</p> <p>14 Q About how much time have you spent</p> <p>15 preparing for today's deposition?</p> <p>16 A I would say the time since November 18,</p> <p>17 which is referenced here, to today, there were</p> <p>18 actually two components. One was preparing for</p> <p>19 the deposition. Another was a bit of a flurry of</p> <p>20 activity in December, I think it was, when a</p> <p>21 couple of reports from Health Canada and from</p> <p>22 the Taher group were published, and I reviewed and</p> <p>23 tried to think about that information as well.</p> <p>24 So just to be as precise as possible, I</p> <p>25 just want to make that clear. It's not -- it</p>	<p>1 paper and the Health Canada statement?</p> <p>2 A No, I didn't.</p> <p>3 Q Did you annotate any of the materials</p> <p>4 that you reviewed?</p> <p>5 A I'm -- I'm not sure. I typically have a</p> <p>6 pen in my hand when I'm reading, so I couldn't say</p> <p>7 that I never underlined anything or -- I just</p> <p>8 don't recall making any -- and I don't know that I</p> <p>9 could find -- if I did look at it in December, I'm</p> <p>10 not sure I could find that copy because I -- I</p> <p>11 tend to print things over when -- and I -- there</p> <p>12 was nothing written that I wanted to retain. I</p> <p>13 didn't write anything that I have used or -- yeah.</p> <p>14 MS. BRANSCOME: We've been going for a</p> <p>15 little over an hour. Is now a good time to take a</p> <p>16 break?</p> <p>17 THE WITNESS: It's a great time.</p> <p>18 THE VIDEOGRAPHER: We are going off the</p> <p>19 record at 10:55 a.m.</p> <p>20 (Recess.)</p> <p>21 THE VIDEOGRAPHER: This begins disc</p> <p>22 number 2 in the deposition of Jack Siemiatycki.</p> <p>23 We're going back on the record at 11:15 a.m.</p> <p>24 BY MS. BRANSCOME:</p> <p>25 Q Before we took the break,</p>
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<p>1 wasn't only preparation. But I -- I guess we're</p> <p>2 talking about a couple of weeks' work in -- since</p> <p>3 November, but between six and ten days maybe,</p> <p>4 something in that ballpark.</p> <p>5 Q And how would -- what would that be in</p> <p>6 terms of hours?</p> <p>7 A Between 40 and 60 hours or -- subject to</p> <p>8 revision, I could -- I could look that up.</p> <p>9 Q Have you billed plaintiffs' counsel for</p> <p>10 that time yet?</p> <p>11 A No, I haven't.</p> <p>12 Q Presumably you will be billing them for</p> <p>13 the time you spend here today during your</p> <p>14 deposition as well, correct?</p> <p>15 A I -- I presume so as well.</p> <p>16 Q You referenced a flurry of activity in</p> <p>17 December related to the Health Canada information</p> <p>18 becoming public.</p> <p>19 Did you produce or generate any type of</p> <p>20 written work product in connection with your</p> <p>21 review of those materials?</p> <p>22 A No, I didn't.</p> <p>23 Q Did you take any notes while reviewing</p> <p>24 the materials that came out in December -- around</p> <p>25 December 2018 related to the Taher manuscript and</p>	<p>1 Dr. Siemiatycki, we were looking at the two bills</p> <p>2 for professional services that have been marked as</p> <p>3 Exhibit 7 and Exhibit 8.</p> <p>4 And so in addition to the 56 hours that</p> <p>5 are on Exhibit 8, the 136 hours on Exhibit 7, and</p> <p>6 the approximately 40 to 60 hours you have spent</p> <p>7 since mid-November of 2018, how much time have you</p> <p>8 spent in connection with your opinions across all</p> <p>9 talc litigation?</p> <p>10 MS. PARFITT: Objection to form.</p> <p>11 THE WITNESS: Including the previous</p> <p>12 case that I was involved in, you're saying?</p> <p>13 BY MS. BRANSCOME:</p> <p>14 Q Yes.</p> <p>15 A Whew. I -- four to six weeks maybe</p> <p>16 or -- I spent, I think, nearly two weeks in LA</p> <p>17 while that case was going on, so that's one big</p> <p>18 block of time. And then I -- at least a month</p> <p>19 full time, the equivalent of, before that. But,</p> <p>20 I'm sorry, I can't be more precise.</p> <p>21 Q What would that be in terms of hours?</p> <p>22 A Hours. Let's say eight hours a day --</p> <p>23 30, 40 -- 400 hours plus or minus 200.</p> <p>24 Q So a range of between 200 to 600 hours,</p> <p>25 do you think?</p>

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<p>1 MS. PARFITT: Object.</p> <p>2 THE WITNESS: It would be more than 200</p> <p>3 for sure. So -- to the best of my recollection,</p> <p>4 it might be between 400 and 600. But...</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q How much have you billed to date for all</p> <p>7 of the work you've done in connection with talc</p> <p>8 litigation?</p> <p>9 A Well, I -- I don't remember.</p> <p>10 MS. PARFITT: Don't guess.</p> <p>11 THE WITNESS: I don't remember a total.</p> <p>12 BY MS. BRANSCOME:</p> <p>13 Q Do you charge \$450 per hour for all</p> <p>14 types of work that you have done in connection</p> <p>15 with the talc litigation?</p> <p>16 A Yes, I do.</p> <p>17 Q Do the fees that you charge in</p> <p>18 connection with your work as an expert witness in</p> <p>19 the talc litigation go directly to you personally?</p> <p>20 A Yes, they do. Well, they go to a</p> <p>21 corporation that -- that I control, as you see in</p> <p>22 the bills.</p> <p>23 Q Do you pay anyone else for the -- using</p> <p>24 the funds that the corporation has received for</p> <p>25 the expert work you've done in connection with the</p>	<p>1 do you currently spend performing work in</p> <p>2 connection with litigation?</p> <p>3 A By presently, can you give me a time</p> <p>4 frame? You don't mean today, I presume. When you</p> <p>5 say -- do you mean in the last year? In the last</p> <p>6 10 years?</p> <p>7 Q Let's say over -- over the past 12</p> <p>8 months, what percent of your professional time was</p> <p>9 spent performing work in connection with</p> <p>10 litigation?</p> <p>11 A Ten to 20 percent ballpark.</p> <p>12 Q And has that percentage of time spent on</p> <p>13 work in connection with litigation changed over</p> <p>14 the past five years, for example?</p> <p>15 A Yes, it's very variable depending on</p> <p>16 requests for participation in litigation. So in</p> <p>17 the past five years, my main contact with</p> <p>18 litigation has been in the ovarian cancer cases,</p> <p>19 but at -- around five years ago, I was also</p> <p>20 working on two other cases in Canada.</p> <p>21 Sorry, what was the question?</p> <p>22 Q Sure. How -- I'll ask a new one.</p> <p>23 How has the percentage of time that --</p> <p>24 A Oh, oh.</p> <p>25 Q -- you spend in connection with work</p>
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<p>1 talc litigation?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: Yes, when I ask someone to</p> <p>4 do some specific tasks, I pay them for that.</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q And are the fees that you pay to other</p> <p>7 individuals for tasks that they do in support of</p> <p>8 your work, do those fees get billed to plaintiffs'</p> <p>9 counsel?</p> <p>10 A No, they don't.</p> <p>11 Q Can you give me an approximation of how</p> <p>12 much you have paid to others from the fees you</p> <p>13 have billed to plaintiffs' counsel?</p> <p>14 A In MDL or in total?</p> <p>15 Q In all of the talc litigation.</p> <p>16 A My guesstimate would be that it's in the</p> <p>17 order of 2 or 3 or 4 percent -- maybe 2 percent of</p> <p>18 the total that I've billed.</p> <p>19 Q So it's fair to say that approximately</p> <p>20 96 to 98 percent of all the fees that have been</p> <p>21 billed to plaintiffs' counsel for your work as an</p> <p>22 expert in the talc litigation will come to you</p> <p>23 personally?</p> <p>24 A Yes.</p> <p>25 Q What percent of your professional time</p>	<p>1 done related to litigation changed?</p> <p>2 A Any litigation, right?</p> <p>3 Q Yes.</p> <p>4 A Or -- or talc litigation?</p> <p>5 Q I'll start with all litigation.</p> <p>6 A So it's -- as I said, it's very variable</p> <p>7 from month to month. And -- and -- I mean, I</p> <p>8 guess over the past five years, it has kind of</p> <p>9 averaged out at about 10 percent of my time, 10 to</p> <p>10 20 percent of my time.</p> <p>11 Q And over the past two years, has all of</p> <p>12 the litigation work you've been doing, has that</p> <p>13 been exclusively focused on talc?</p> <p>14 A Yes.</p> <p>15 Q The report that -- sorry, the report you</p> <p>16 prepared in connection with the MDL is not the</p> <p>17 first expert report you have generated with</p> <p>18 respect to a potential link between talc and</p> <p>19 ovarian cancer, correct?</p> <p>20 A That's correct.</p> <p>21 Q You produced a report in connection with</p> <p>22 the talcum powder litigation dated October 4th,</p> <p>23 2016, correct?</p> <p>24 A That's correct.</p> <p>25 Q If you could turn in your binder there</p>

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<p style="text-align: right;">Page 58</p> <p>1 to tab 2.</p> <p>2 A In this big binder?</p> <p>3 Q Yes, please.</p> <p>4 Is the document behind tab 2 your expert</p> <p>5 report dated October 4th, 2016, that related to</p> <p>6 the talcum powder litigation?</p> <p>7 A Yes, it is.</p> <p>8 MS. BRANSCOME: I would like to mark</p> <p>9 that as Exhibit 9.</p> <p>10 (Exhibit No. 9 was marked for</p> <p>11 identification.)</p> <p>12 BY MS. BRANSCOME:</p> <p>13 Q The report marked as Exhibit 9 was not</p> <p>14 drafted for a particular case; is that correct?</p> <p>15 A I -- I -- I'd have to defer -- I'm not</p> <p>16 exactly sure sometimes whether these reports refer</p> <p>17 to a specific case or not.</p> <p>18 Q Okay. Let me do it this way: What was</p> <p>19 the question that you were attempting to answer in</p> <p>20 the report that has been marked as Exhibit 9?</p> <p>21 A So the question was the generic question</p> <p>22 of whether there is a causal relationship between</p> <p>23 use of talcum powder products and ovarian cancer.</p> <p>24 Q And specifically, the report marked as</p> <p>25 Exhibit 9, were you looking specifically at</p>	<p style="text-align: right;">Page 60</p> <p>1 specific to the Echeverria case, correct?</p> <p>2 A Correct.</p> <p>3 Q So the expert report that described the</p> <p>4 opinions that you were offering in that case is</p> <p>5 the one that we have just marked as Exhibit 9. Is</p> <p>6 that fair?</p> <p>7 MS. PARFITT: Objection. Form.</p> <p>8 THE WITNESS: I -- I'm -- I'm hesitating</p> <p>9 because I'm not sure what the significance of the</p> <p>10 phrase "the expert report that you offered" is. I</p> <p>11 didn't -- I didn't in a sense offer this report</p> <p>12 for -- at that trial. I testified at that trial,</p> <p>13 and they had this expert report available to them.</p> <p>14 BY MS. BRANSCOME:</p> <p>15 Q Okay. Let me ask it this way: You</p> <p>16 generated an expert report specific to the MDL,</p> <p>17 correct?</p> <p>18 A Yes.</p> <p>19 Q And we are going to look at that --</p> <p>20 A Yes.</p> <p>21 Q -- but that is a report that is dated at</p> <p>22 some point in 2018, correct?</p> <p>23 A Correct.</p> <p>24 Q Did you generate an expert report at any</p> <p>25 time in between the expert report that you</p>
<p style="text-align: right;">Page 59</p> <p>1 perineal or genital use of talc?</p> <p>2 A That was the focus, yes.</p> <p>3 Q Did your 2016 report address any cancer</p> <p>4 risk associated with the inhalation of talc?</p> <p>5 A Not that I recall. It certainly wasn't</p> <p>6 a focus. There may have been some reason to</p> <p>7 allude to that issue, but I can't recall that</p> <p>8 it -- that there was.</p> <p>9 Q Okay. You had your deposition taken on</p> <p>10 December 15th and 16th, 2016, correct?</p> <p>11 A I believe so.</p> <p>12 Q And that deposition was for two specific</p> <p>13 cases, the Oules and the Daniels case, correct?</p> <p>14 A I guess so. But again, I -- that --</p> <p>15 I'm -- I don't recall exactly which cases.</p> <p>16 Q You also have testified at trial in a</p> <p>17 case involving allegations about Johnson's Baby</p> <p>18 Powder, correct?</p> <p>19 A That's correct.</p> <p>20 Q And that was the Echeverria case?</p> <p>21 A Yes, it was.</p> <p>22 Q And you testified in trial in August of</p> <p>23 2017, correct?</p> <p>24 A Correct.</p> <p>25 Q You did not issue an expert report</p>	<p style="text-align: right;">Page 61</p> <p>1 generated there in October 2016 and the expert</p> <p>2 report you have supplied that's dated November</p> <p>3 2018?</p> <p>4 A No, I did not.</p> <p>5 Q All right. So if I may, I would like to</p> <p>6 actually mark your copy of your 2018 report. And</p> <p>7 that will be marked as Exhibit 10, if you have</p> <p>8 that in front of you.</p> <p>9 (Exhibit No. 10 was marked for</p> <p>10 identification.)</p> <p>11 (Counsel conferring.)</p> <p>12 BY MS. BRANSCOME:</p> <p>13 Q To be clear, for the record, I'm marking</p> <p>14 as Exhibit 10 your MDL expert report, but it is</p> <p>15 your copy.</p> <p>16 A Yes.</p> <p>17 Q Okay. And as I understand it, the copy</p> <p>18 that you brought with you here today that's now</p> <p>19 been marked as Exhibit 10 contains some</p> <p>20 corrections. Is that -- is that fair?</p> <p>21 A Yes.</p> <p>22 Q Could you please walk me through the</p> <p>23 corrections that you have made to your 2018 MDL</p> <p>24 report that has been marked as deposition</p> <p>25 Exhibit 10.</p>

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<p>1 A Yes. So the first is on page 47. And</p> <p>2 in the first full paragraph that begins with</p> <p>3 "Table 9," on the fourth line --</p> <p>4 Q Let me pause you there for a moment,</p> <p>5 Dr. Siemiatycki. Are we both looking at page 47?</p> <p>6 A Now, I -- I'm not sure whether I printed</p> <p>7 this in a way that is not -- does not correspond</p> <p>8 to the version that you have. I'm sorry. I</p> <p>9 printed this just for my own use, so I didn't --</p> <p>10 Q No, looking at it, it looks similar.</p> <p>11 A Oh, okay.</p> <p>12 Q So why don't you direct me to the</p> <p>13 specific correction. I thought you were referring</p> <p>14 to the image of Table 9.</p> <p>15 MS. PARFITT: No, no. I think we're</p> <p>16 all on the same -- it's the same one you have --</p> <p>17 THE WITNESS: Okay.</p> <p>18 MS. PARFITT: -- on your thumb drives.</p> <p>19 THE WITNESS: Okay.</p> <p>20 BY MS. BRANSCOME:</p> <p>21 Q All right, we'll start again. So,</p> <p>22 Dr. Siemiatycki, if you could identify for me the</p> <p>23 corrections that you are making to your MDL report</p> <p>24 from November 2018.</p> <p>25 A Right. So on page 47, the first full</p>	<p>1 your copy of your report that there were other</p> <p>2 handwritten annotations.</p> <p>3 A Yeah.</p> <p>4 Q Can you please walk me through -- unless</p> <p>5 it's voluminous, in which case we can do it after</p> <p>6 a break -- any notations that you have made in</p> <p>7 your copy of your MDL report.</p> <p>8 A It's not voluminous. I didn't make</p> <p>9 many. One is on page 49. And in the middle of</p> <p>10 the page in italics, there is a misconception</p> <p>11 counting, et cetera, and just before that, I was</p> <p>12 talking about hospital-based studies and</p> <p>13 population-based studies. So the section that</p> <p>14 begins on page 48 is about hospital-based versus</p> <p>15 general population-based studies. And I made a</p> <p>16 note to myself after that -- at the end of that</p> <p>17 section, also --</p> <p>18 I mean, do you want me to quote what I</p> <p>19 wrote?</p> <p>20 Q Yes, please.</p> <p>21 A Sure. I said: "Also the basin for</p> <p>22 hospital controls may differ from the basin for</p> <p>23 cases."</p> <p>24 Q And what did you mean by that?</p> <p>25 A So, you're familiar with the idea, a</p>
Page 63	Page 65
<p>1 paragraph, the fourth line, there are some</p> <p>2 numbers. It says "1.25," and then in parentheses,</p> <p>3 there is a 1.0 that was really a literal typo.</p> <p>4 Someone's -- my fingers were too heavy, and the</p> <p>5 one -- the first 1.0 should be dropped, and so the</p> <p>6 correct number is 1.15 to 1.36. Okay?</p> <p>7 The next one -- I'm sorry. Oh, the next</p> <p>8 one is on page 45, so a couple of pages earlier,</p> <p>9 in the second line -- are you with me? -- the</p> <p>10 sentence that begins "While the Terry 2013." It</p> <p>11 should be the Berge -- "While the Berge" -- the</p> <p>12 first Terry -- I'm just thinking out loud again.</p> <p>13 Whether in fact the Terry was the correct --</p> <p>14 anyway, yesterday when I was correcting this</p> <p>15 quickly, I thought that it -- that I had</p> <p>16 miswritten "Terry 2013" in that sentence and that</p> <p>17 it should have been Berge 2018.</p> <p>18 Do you mind if I look at this again at</p> <p>19 lunchtime and just verify which I was referring</p> <p>20 to? I'm now confusing myself about that.</p> <p>21 Q Not a problem. We can come back to that</p> <p>22 after -- either the next break or the lunch break.</p> <p>23 A And that -- those are the only</p> <p>24 corrections I picked up as I was going through it.</p> <p>25 Q I noticed as you were flipping through</p>	<p>1 hospital-based study? There are actually</p> <p>2 different types of hospital-based studies, which</p> <p>3 is something that has not come out in, really, in</p> <p>4 any of the discussion of this literature.</p> <p>5 But one of the problems with hospital-</p> <p>6 based studies is that when you choose a control</p> <p>7 group, let's say for a series of ovarian cancer</p> <p>8 cases from a given hospital, and you go to a</p> <p>9 different ward in that hospital to look for</p> <p>10 controls who are not -- don't have ovarian</p> <p>11 cancer -- the reasons for referral and the -- the</p> <p>12 pattern of patients coming to hospitals differs</p> <p>13 for different diseases. So serious -- it</p> <p>14 generally is the case that serious diseases in</p> <p>15 specialized hospitals tend to come from a wider</p> <p>16 geographic and social area than cases of traffic</p> <p>17 accident injuries or things that are treated in</p> <p>18 general hospitals more easily.</p> <p>19 And if you just take a series of cases</p> <p>20 of ovarian cancer and go to the emergency</p> <p>21 department to choose controls or you go to the GI</p> <p>22 surgery department where they do appendectomies</p> <p>23 routinely or something like that, you're picking</p> <p>24 up populations who are quite different.</p> <p>25 And this is one of the disadvantages of</p>

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<p>1 a hospital-based control strategy, and it's one of 2 the reasons why, in general, epidemiologists favor 3 population-based studies rather than hospital -- 4 case control studies, population-based case 5 control studies, rather than hospital-based case 6 control studies, because the cases and the 7 controls -- one of the requisites in a case 8 control design is that the patients -- the cases 9 and the controls should represent the same study 10 base, the same basin of people who if they were 11 cases with the disease in question, ovarian 12 cancer, this is where they would end up, and all 13 of them would end up there. 14 Q Are there any studies that were relevant 15 to your analysis for your MDL report that you 16 think this particular criticism that you have just 17 explained applies to? 18 A I'm not sure. I didn't examine them 19 from that point of view. 20 In this section of my report, it was 21 kind of a generic discussion of the issue of -- of 22 the merits of hospital-based versus population- 23 based studies. 24 Q Okay. Do you have any other annotations 25 that you made in your copy of your MDL report?</p>	<p>1 THE VIDEOGRAPHER: We're going back on 2 the record at 11:41 a.m. 3 BY MS. BRANSCOME: 4 Q Do you have any other annotations there 5 with you on your copy of your report? 6 A No. I have one other green sticky on 7 page 67, but there's nothing written on that page, 8 and I don't remember why I put that sticky there. 9 Q Okay. The report that we just marked as 10 Exhibit 10, does that define the scope of your 11 opinions in the MDL? 12 A The scope of my opinions. It defines my 13 opinions, yes. 14 Q Does it contain all of the opinions that 15 you intend to offer at any trial or hearing in the 16 MDL? 17 A I mean, I guess if I'm asked a question 18 that veers off from something I said in my report, 19 and I address the question, would that be 20 considered going off -- you know, offering an 21 opinion that is not in my report? 22 It's just that -- I'm just not sure 23 about the technicality of your question. I mean, 24 I will offer -- I will answer questions even if 25 they lead off the content of my report.</p>
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<p>1 A At the bottom of that same page, 49, I 2 wrote, quote, "Borenstein." And right now I'm -- 3 oh, yes. So this misconception about counting the 4 number of statistically significant results as a 5 valid way of assessing consistency of results 6 among different studies is a basic flaw in the 7 conduct and interpretation of how to review a 8 series of studies. 9 It's well known. I've known and I -- I 10 said it in my report that this is absolutely not 11 the way to synthesize evidence from multiple 12 studies, to count the number of significant ones. 13 And in addition to me saying it and many others, I 14 thought that I could -- if you asked me questions 15 about it or challenged my opinion on that score, I 16 could quote the textbook on meta-analysis, which 17 gives some good examples of why that's wrong. 18 MS. PARFITT: Let's stop here for a 19 minute -- 20 MS. BRANSCOME: If we could go off the 21 record. 22 MS. PARFITT: -- and go off the record. 23 THE VIDEOGRAPHER: We're going off the 24 record at 11:39 a.m. 25 (Pause.)</p>	<p>1 Q As you sit here today -- 2 A Yes. 3 Q -- does the report that has been marked 4 as Exhibit 10 contain all of the opinions that you 5 have formed as of today about which you would 6 intend to testify at trial or a hearing on this 7 matter? 8 A I -- I believe so. 9 Q What was the question that you were 10 asked to answer in connection with the report you 11 generated in 2018? 12 A I guess I -- I'll just refer back to 13 what it says in the report: "Can application of 14 talcum powder products in the perineal region 15 cause ovarian cancer?" 16 Q Is that question different from the 17 question you were answering in your 2016 report? 18 A I -- I don't see them as different. 19 Q You would agree with me, though, that 20 there are differences between the report that you 21 produced in November 2018 and the report that you 22 produced in October 2016? 23 MS. PARFITT: Objection. Form. Vague. 24 THE WITNESS: Yes, there are some 25 differences.</p>

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<p style="text-align: right;">Page 70</p> <p>1 BY MS. BRANSCOME: 2 Q When you began drafting the report 3 that's been marked there as Exhibit 10, your MDL 4 report, did you begin by using your 2016 report as 5 an initial draft? 6 A Yes. But I also had some ideas about 7 new things that I would want to do. Sort of 8 coming out of the Echeverria experience, I 9 realized that there were -- there were a couple of 10 errors in that -- my original report that I wanted 11 to correct. There were ways of doing the analyses 12 that, on reflection, I thought were not optimal 13 and that I could improve on, even if I anticipated 14 that the bottom line results would not change 15 much. But when I came to actually drafting the 16 text, I certainly used the previous report as a 17 primary source for revising -- for -- for drafting 18 the new one. 19 Q You mentioned that you wanted to make 20 some modifications because there were things in 21 the 2016 report that were either not optimal or 22 were errors. 23 Were any of the modifications that you 24 made done at the suggestion of plaintiffs' 25 counsel?</p>	<p style="text-align: right;">Page 72</p> <p>1 sequence, and I use both of them now but in 2 different places. 3 But -- so is your question, is it 4 exactly the same computer that all the files were 5 kept on or -- is that the sense of your question? 6 BY MS. BRANSCOME: 7 Q How about I ask it this way: Can you 8 describe for me the process by which you drafted 9 your 2018 report that's been marked as Exhibit 10? 10 A So I guess there were two parallel 11 things going on, or maybe more. One was to do 12 some reanalyses of the statistical meta-analysis. 13 And so that I initiated at a certain point 14 between -- probably in 2018. 15 At the same time, and I'm not sure if 16 this was after or before the statistical analyses 17 were started, I looked at the old draft. I 18 reviewed what was there, what I thought were 19 weaknesses in the way of expressing things or 20 things that could be brought to the report that 21 would enhance the clarity or the force of the -- 22 the exposition, and I started redrafting. So I'm 23 not sure if that answers your question. 24 Q Did you personally type the words that 25 are contained in Exhibit 10?</p>
<p style="text-align: right;">Page 71</p> <p>1 MS. PARFITT: Objection. 2 THE WITNESS: No. 3 BY MS. BRANSCOME: 4 Q So any of the changes that you made 5 between your 2016 report and the MDL report in 6 2018, were those all at your own prompting? 7 A Yes. 8 MS. PARFITT: Objection. Form. 9 THE WITNESS: Yes. 10 BY MS. BRANSCOME: 11 Q Did you work in the same computer file 12 to draft the 2018 report from start to finish? 13 MS. PARFITT: Objection. Form. 14 THE WITNESS: You're -- you're referring 15 to the text, not the statistical analyses, which 16 were done in a separate -- I mean, they -- they -- 17 the statistical analyses were based on the 18 addendum that I presented to you, and those are 19 kept on a FileMaker software, which is not on my 20 personal computer, but that my assistant has 21 access to. 22 But as far as the text is concerned -- 23 yeah, I think it was the same computer, but I've 24 changed computers since then, so I'm just 25 hesitating because I'm trying to think of the time</p>	<p style="text-align: right;">Page 73</p> <p>1 A All -- maybe all of them, and maybe 2 there were some paragraphs that I handwrote 3 because I was on a plane or a train, and when I 4 got back to the office, I asked someone to type up 5 that paragraph or two. But basically it was done 6 by me. 7 Q And did you save draft versions along 8 the way? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: Not really. Not -- 11 certainly not systematically. I didn't see any 12 reason to save discarded versions of things. 13 Yeah. 14 BY MS. BRANSCOME: 15 Q Did you conduct a new literature review 16 in connection with the 2018 report? 17 A I knew that I had all of the literature 18 that was pertinent and published as of 2016. 19 Updating what was available was partly done by 20 asking my research assistant to do a PubMed search 21 of anything new on the topic; asking the lawyers 22 if they had come across anything new in the past 23 year; my own antenna of knowing a lot of 24 epidemiologists and people who work in this area, 25 whether they are aware of anything. So sort of an</p>

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<p style="text-align: right;">Page 74</p> <p>1 informal updating process from many branches. 2 Q Did plaintiffs' counsel provide you with 3 studies that had come out since you had generated 4 your 2016 report? 5 A I think they sort of pointed me to a 6 couple of things that I didn't have at the time. 7 I think one was the Penninkilampi review. 8 We're talking about the epidemiology 9 literature or everything? Because the 10 epidemiology literature I was pretty much in 11 control of through my networks and my people and 12 so on. 13 The stuff that I asked counsel to help 14 with was identifying literature in the areas of 15 toxicology, composition of talcum powder products, 16 mechanistic research that would bear on the issue. 17 So I asked them if they would provide me any new 18 data that they had available on those topics. 19 Q Do you consider yourself an expert in 20 toxicology? 21 A No. I'm sufficiently familiar to be 22 able to integrate the expertise of -- of real 23 experts. 24 Q Do you consider yourself an expert on 25 the composition of talc?</p>	<p style="text-align: right;">Page 76</p> <p>1 statistical analysis for your meta-analysis? 2 A It's -- I think it's called 3 Meta-Analysis, but -- it's called Comprehensive 4 Meta-Analysis, Version 3. It's listed in my 5 report on page 34. 6 Q And is that the only software that you 7 used to perform the statistical analyses in your 8 report? 9 A It's the only software that I used to 10 perform the meta-analyses. Are there any other -- 11 I'm just trying to think if there are any other 12 analyses in the report besides meta-analyses or 13 statistical. 14 There were a couple of studies, and I -- 15 I couldn't point them out just this minute, that 16 did not provide full information allowing -- that 17 didn't provide full information on odds ratios or 18 relative risks in a format that was useful for the 19 meta-analysis. And -- but they did provide the 20 numbers of cases and controls who were exposed and 21 unexposed. And that would typically -- I think in 22 at least one instance, maybe two, but at least one 23 instance, there was a situation where they 24 provided odds ratio estimates in different 25 categories of usage of talc or either different</p>
<p style="text-align: right;">Page 75</p> <p>1 A No. 2 Q And do you consider yourself an expert 3 on potential biological mechanisms of the 4 development of ovarian cancer? 5 A No. 6 Q Other than being aware of the opinions 7 of others in those particular fields, are you 8 offering any expert opinions in toxicology, the 9 composition of talc, or the biological mechanism 10 by which ovarian cancer may develop? 11 A I'm -- 12 MS. PARFITT: Objection. Form. 13 Go ahead. 14 THE WITNESS: I'm -- I reviewed the 15 information that I was provided, and I took note 16 of the types of evidence that are available in 17 those domains, and I used it mainly in thinking 18 about biological plausibility of the association. 19 It -- those areas of evidence did not in any way 20 influence my opinions about the strength and 21 consistency and so on of the epidemiological 22 evidence. 23 BY MS. BRANSCOME: 24 Q Did you -- oh, before I forget, what is 25 the name of the software that you used to do the</p>	<p style="text-align: right;">Page 77</p> <p>1 durations or different amounts used per day or 2 something like that, but didn't summarize that in 3 an overall ever-used-it-at-all versus 4 never-used-it, which was what I was looking to use 5 in the meta-analysis. 6 And I think in those -- in that 7 instance, I did almost a hand calculation. 8 Because it's pretty straightforward how you do 9 this, just re- -- picking the numbers in their 10 tables and recalculating the overall odds ratio. 11 But this is a few years ago, and I -- 12 I -- I would have to go back and review that, but 13 it was -- I think in the other meta-analyses, 14 Berge and Penninkilampi, which were carried out 15 completely independently of mine, and I didn't 16 know about theirs, I think they had to do 17 something similar and arrived at the same answers. 18 So -- but, no, I mean there was no -- no 19 other statistical package used. That kind of 20 calculation can be done by hand. 21 Q How would -- how would I, if I'm looking 22 at your report, identify which studies you 23 actually calculated the odds ratio or relative 24 risk that you input into your meta-analyses? 25 A I -- I -- I'd have to look at it at</p>

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<p>1 lunchtime, if you don't mind, and see if there was 2 one. 3 There was one. I don't know if that was 4 retained in the end or if -- I'm sorry. It's -- 5 Q When you say you don't know if a study 6 was retained in the end, are there studies that 7 you considered including in your meta-analysis and 8 ultimately did not? 9 A Only if they didn't provide evidence on 10 the relationship between talcum powder used in the 11 perineal area and ovarian cancer. 12 Q All right. If you wouldn't mind looking 13 at that at lunch, we will come back -- 14 A Yes. Thank you. 15 Q -- to that after the lunch break. 16 THE WITNESS: Someone make a note for 17 me. 18 BY MS. BRANSCOME: 19 Q Did you -- 20 MS. PARFITT: Yes, a note. 21 BY MS. BRANSCOME: 22 Q Did you personally conduct the 23 meta-analysis that was performed as part of your 24 2018 report? 25 A No, I did not do the --</p>	<p>1 from one to another was perfectly in line with 2 what I would expect. 3 Furthermore, the results that we 4 obtained are almost identical to the results that 5 others have independently obtained doing 6 meta-analyses on these topics using basically the 7 same studies. Sometimes the difference of -- 8 minor differences of which result from each study 9 they selected, but basically the results are so 10 similar that I'm confident that there was no 11 glitch. 12 Q Did you save the results of these 13 sensitivity analyses? 14 A Do you mean the output from the computer 15 software for each one? Is that what you're -- 16 Q Is there any way from the materials that 17 you have produced in connection with your report 18 for someone to replicate the sensitivity analyses 19 that you performed? 20 MS. PARFITT: Objection. Form. 21 THE WITNESS: Well -- I reproduced in 22 the report a few plots of -- that come straight 23 out of the program. So for those, it's absolutely 24 replicatable. Anybody can then go to the package 25 and put -- punch in the same input, and they'll --</p>
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<p>1 Q Who did that? 2 A My student. 3 Q And what is your student's name? 4 A Mengting, M-E-N-G-T-I-N-G, Xu, X-U. 5 Q And -- and what are -- is it Mr. or 6 Dr. Xu? 7 A It's -- she's a Ph.D. student at the 8 moment. She will be a doctor. 9 Q What are her qualifications for 10 conducting a meta-analysis? 11 A She is very skilled at statistical 12 analyses and at -- at computer packages. I'm not 13 sure if she's taken a course in meta-analysis 14 specifically, but it's not rocket science to do 15 that with a package like the one we have. 16 Q Did you verify that the meta-analysis 17 was performed correctly using the software? 18 A I looked at the results in various ways 19 to assure myself that everything looked good. By 20 looking good, I mean that there was internal 21 coherence, like she carried out many different 22 meta-analyses under different conditions and -- 23 not different conditions, but including some 24 studies and excluding studies -- these are called 25 sensitivity analyses -- and the pattern of results</p>	<p>1 they'll get the same output. For the -- I didn't 2 do that for every single sensitivity analysis, 3 just for economy -- to save the reader the burden 4 of that. But I'm pretty sure -- I'm pretty sure 5 that Mengting kept files of each of those 6 analyses. 7 BY MS. BRANSCOME: 8 Q Did anyone else -- you mentioned a 9 research assistant helped you with PubMed 10 searches. Who was the research assistant? 11 A She's a woman, who was with me for 30 12 years or so, who was basically the bibliographic 13 expert in our team and helped people find articles 14 and do things necessary, like PubMed searches and 15 so on. So she -- while she was here -- she 16 retired a year or so ago. While she was here, I 17 asked her to look at the ovarian cancer/talc 18 thing, and she dug out some -- she found some 19 articles for me. 20 Q Is that Sally Campbell? 21 A Yes, it is. 22 Q Okay. After Ms. Campbell retired, did 23 anyone else help you perform literature searches? 24 A Not in a routine way for sure. If I 25 wanted to find a specific article that I knew</p>

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<p>1 about, I would typically ask my student Mengting 2 to dig it out and print it for me. 3 Q So in addition to Ms. Campbell and 4 Ms. Xu -- 5 A Xu, yes. 6 Q -- did anyone else help prepare the 7 materials that are in your 2018 report? 8 A Yes. So I have another research 9 assistant who's been with me even longer than 10 Sally Campbell, who retired a month ago, and her 11 name is Lesley Richardson. And she set up and 12 maintained the database system in which we 13 integrated all of the results that are in that 14 addendum that I provided you, and that involved 15 reviewing each article and taking every single 16 result and plugging it into this software. 17 Q Did Ms. Richardson exercise any of her 18 own judgment in selecting which data to include in 19 the meta-analyses? 20 A The instruction was to extract 21 everything. Simple instructions can become 22 difficult in operation. And some of the 23 frustration in this area and some of the reason 24 why there is some variability in which studies and 25 which results are included in different</p>	<p>1 Q Okay. And you mentioned reviewing the 2 materials that came out in connection with Health 3 Canada and the Taher manuscript, and we'll talk 4 about that in more detail, but did anything you 5 reviewed since the production of your 2018 report, 6 has any of that changed your opinions or any of 7 the information that is contained in your MDL 8 report? 9 A It doesn't really change anything. I 10 would say that the Health Canada report reinforces 11 the notion that this issue is becoming a front 12 burner issue for public health agencies. But 13 it -- since I didn't explicitly address that 14 question in my report, I would say it doesn't 15 change anything that's in my report. 16 Q Do you intend to offer expert opinions 17 about the different positions of the different 18 public agencies and the relative importance of a 19 potential connection between talc and ovarian 20 cancer? 21 MS. PARFITT: Objection. Form. 22 THE WITNESS: Did I intend -- while 23 writing my report, do you mean, to make -- no. I 24 don't think that those agencies and those 25 positions necessarily reflect the most up-to-date</p>
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<p>1 meta-analyses occur because authors are sometimes 2 cryptic about what they say about their data and 3 their results. And specifically things like what 4 kind of talc use a certain table describes is not 5 always perfectly clear. 6 And so she would need to make a judgment 7 sometimes as to whether this result pertained to 8 all use of talc in the perineal area or only 9 powdering, excluding sanitary napkins or other -- 10 sometimes it -- there's ambiguity in the write-up 11 of these things that therefore requires -- 12 required some judgment on her part. And several 13 of these things she would ask my opinion about, 14 and we would discuss it and say, Well, it looks 15 like this or it looks like that, and let's go with 16 this interpretation. 17 Q Okay. And at the end of the day, 18 despite receiving help from others in developing 19 your 2018 report, do you personally stand behind 20 everything that is in the report? 21 A Yes. Barring more typos. I know that 22 every time I look at anything I've ever written 23 or, you know, things that are expressed not in the 24 most clear way. But, yes, I stand behind 25 everything.</p>	<p>1 science, and I think the most up-to-date science 2 is in the science community through publications 3 and so on, and public health policies tend to lag 4 behind scientific knowledge. 5 BY MS. BRANSCOME: 6 Q Are there instances where public health 7 policies are more conservative than the scientific 8 literature out of sort of a principle of 9 precaution? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: Sorry, I'm not sure I 12 understand the question. 13 BY MS. BRANSCOME: 14 Q Sure. 15 Are there examples where the public 16 health policy is actually, for instance, more 17 protective than the science might support because 18 the public health agency is exercising an 19 abundance of caution? 20 MS. PARFITT: Objection. Form. 21 THE WITNESS: I -- I believe so. I 22 mean, I've not done any kind of survey of how 23 public health policy in, you know, Sweden over 24 Argentina or everywhere -- you're talking about 25 generally in the world public health or are you</p>

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<p>1 talking about United States or -- but I -- I</p> <p>2 imagine there are instances like that, and I think</p> <p>3 there is a strand in public health to be</p> <p>4 precautionary in developing policies. But I'm not</p> <p>5 sure it's universal. I just don't know.</p> <p>6 BY MS. BRANSCOME:</p> <p>7 Q You have a References section in your</p> <p>8 report. It begins at page 109, if you need to</p> <p>9 refer to it.</p> <p>10 How did you maintain all of the</p> <p>11 documents that are identified under that list?</p> <p>12 It's quite voluminous.</p> <p>13 A So let me --</p> <p>14 Q And by that, I mean did you keep hard</p> <p>15 copies? Do you keep electronic copies?</p> <p>16 A Okay. So the first thing I'll point out</p> <p>17 is that I deliberately didn't call it a reference</p> <p>18 section. You'll see that it's called a</p> <p>19 Bibliography.</p> <p>20 Q Could you turn to page 109 in your</p> <p>21 report.</p> <p>22 A That -- that's where I am.</p> <p>23 Q Could you turn to the page right before</p> <p>24 that.</p> <p>25 A Oh. Ah, yes, I see that.</p>	<p>1 A So, yeah, yeah.</p> <p>2 Q -- Dr. Siemiatycki, is how -- how do you</p> <p>3 maintain all of the documents that are listed in</p> <p>4 your reference section? Do you main hard copies?</p> <p>5 Do you keep electronic copies?</p> <p>6 A It's a bit of a mix and match of</p> <p>7 electronic and hard copies. And these are all the</p> <p>8 materials that were collected over the years, you</p> <p>9 know, I would say from the beginning of my</p> <p>10 involvement in the previous trial and so on, that</p> <p>11 concern talc and ovarian cancer, including</p> <p>12 materials that were provided by the lawyers and</p> <p>13 materials that we found.</p> <p>14 I prefer to work with paper -- I prefer</p> <p>15 to read paper, but at a certain point, that gets</p> <p>16 overwhelming, and the material -- I can't tell you</p> <p>17 right now for sure that everything here is -- that</p> <p>18 I have it electronically in a file or that I have</p> <p>19 it in paper.</p> <p>20 Q There are different sections of your</p> <p>21 References section. You have Bibliography Part A,</p> <p>22 B, so on and so forth. Who made the decision of</p> <p>23 which articles or documents fell into which of</p> <p>24 the -- of each category?</p> <p>25 A I -- I guess I made it, but it was</p>
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<p>1 Q What is the page -- you have that as</p> <p>2 page 108?</p> <p>3 A Yes, I have that page with the word</p> <p>4 "References" on page 108. Section 16.</p> <p>5 Q Perhaps we could check at the break. My</p> <p>6 page numbering got off of yours at some point.</p> <p>7 A Okay.</p> <p>8 Q But in any event, you do have a</p> <p>9 Section 16 that's titled "References," correct?</p> <p>10 A Yes. Yes, I do. I do.</p> <p>11 Okay. My -- my conscious volition was</p> <p>12 to call this a bibliography, and the word</p> <p>13 "references" got in -- into the heading of this</p> <p>14 section.</p> <p>15 And the reason for that distinction is</p> <p>16 that I have not -- not everything that is listed</p> <p>17 is referred to in the text of my report. So</p> <p>18 technically speaking, a reference section should</p> <p>19 be those materials that you refer to in your</p> <p>20 report. And this is not what I have here. And</p> <p>21 that's why I -- consciously I wanted to call this</p> <p>22 a bibliography, and somehow the word "references"</p> <p>23 got -- when they -- when we were compiling it --</p> <p>24 anyways.</p> <p>25 Q Okay. So my question again --</p>	<p>1 pretty self-evident. The material in Part A is</p> <p>2 material that is generally publicly available.</p> <p>3 It's easy to identify that. And the materials in</p> <p>4 Part B is material that is not publicly available.</p> <p>5 And all of that came from the lawyers, I think.</p> <p>6 Q So that was going to be one of my</p> <p>7 questions. Did all of the materials identified in</p> <p>8 Bibliography Part B come to you from plaintiffs'</p> <p>9 counsel?</p> <p>10 A Okay. So let me look through this</p> <p>11 quickly.</p> <p>12 MS. PARFITT: Mm-hmm. Go ahead.</p> <p>13 THE WITNESS: (Peruses document.)</p> <p>14 I think so. I -- I think all of it came</p> <p>15 from plaintiffs' counsel.</p> <p>16 BY MS. BRANSCOME:</p> <p>17 Q I'm not going to ask you about all of</p> <p>18 these, but I noticed on page, at least in my copy,</p> <p>19 135, maybe 134 on yours, there's reference to the</p> <p>20 Berg v. Johnson & Johnson case.</p> <p>21 Do you see that?</p> <p>22 A Yes, I see that.</p> <p>23 Q What relevance is it to you as an</p> <p>24 epidemiologist evaluating the potential risk of</p> <p>25 ovarian cancer from perineal use of talc to look</p>

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<p>1 at the final jury instructions, judgment, and 2 verdict form from the Berg case? 3 A I'm not sure. I relied on plaintiffs' 4 counsel to decide what they thought it would be 5 pertinent for me to be aware of. So these were 6 documents that they thought would be pertinent for 7 me to -- to be aware of, and I can't say why, and 8 I don't remember -- frankly, I don't remember 9 these documents. 10 Q As a scientist, do you typically 11 consider jury instructions in forming an opinion 12 with respect to risk of the use of a product in 13 epidemiology? 14 MS. PARFITT: Objection. 15 THE WITNESS: Outside of a legal -- no, 16 we wouldn't have access to it or -- no, it never 17 comes up. 18 BY MS. BRANSCOME: 19 Q As you sit here today, can you come up 20 with any reason why the jury instructions in a 21 case would be relevant to you in evaluating the 22 question you were asked to answer, which is 23 whether or not there is a risk of ovarian cancer 24 from the perineal use of talc? 25 MS. PARFITT: Objection. Form.</p>	<p>1 informative of your opinions? 2 A No. There's no way for anyone else to 3 know that. 4 Q Okay. Did you ask plaintiffs' counsel 5 for specific company documents, using that term 6 loosely, to refer to documents that are kept 7 internally within the various companies at issue 8 in this litigation? 9 A I asked to be sent any information they 10 had about the composition of talcum powder 11 products, historically as well as currently, but 12 actually mainly historic -- I was mainly 13 interested to know what was the history of the 14 composition of talcum powder products. 15 And so many of these materials that they 16 sent me -- and I can't tell you which ones because 17 I don't identify them with these obscure numbers, 18 they don't mean anything to me -- but some of them 19 dealt with internal company documents or internal 20 reports that discussed different types of talc -- 21 of powdering products, whether talc products or 22 cornstarch products in different eras, when they 23 started and when, what the market share was in 24 different eras. So I was interested in that to 25 get a sense of what were the women exposed to who</p>
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<p>1 THE WITNESS: You're asking me to 2 speculate as to why plaintiffs' counsel would have 3 sent this to me? 4 BY MS. BRANSCOME: 5 Q I'm asking -- 6 A Is that what you're asking? 7 Q I'm asking if you, as the scientist 8 whose name is on this expert report, can you think 9 of any reason why that would be informative to you 10 as a scientist? 11 A If I had it in front of me, I might 12 recognize something in there that would make it 13 relevant. But I -- I don't know what is typically 14 in such jury instructions. I don't know how -- 15 what the sweep is of those things. I'm just not 16 sure. So I -- I can't answer the question. 17 Q As you sit here today, do you recall 18 reading the final jury instructions from Berg -- 19 A I don't -- 20 Q -- v. Johnson & Johnson? 21 A I don't actually recall reading it. 22 Q Okay. So is there any way for someone 23 reviewing your report to identify within the 24 reference section, Part B, which of these 25 documents you, Dr. Siemiatycki, found relevant and</p>	<p>1 were part of these epidemiologic studies. 2 Q Do you rely on any of the information 3 that you obtained from documents in Part B of your 4 reference list as a basis for forming your expert 5 opinion in the MDL? 6 A No. No. 7 Q Have you viewed any of the deposition 8 transcripts of the depositions that have been 9 taken in the MDL? 10 A I have looked at a few of them. 11 Q And which deposition transcripts have 12 you reviewed? 13 A Plunkett, McTiernan, is it? And Singh. 14 Not fully -- not the entire transcripts, but 15 portions thereof. Blount. I've seen excerpts 16 from, is it, Hopkins? And a table from Pier, but 17 not the full text. I didn't review the full text 18 -- transcript. There may be one or two more, and 19 I can't recall right now. 20 Q Okay. Focussing specifically on the 21 expert deposition transcripts from the MDL, did 22 you ask specifically for Drs. Plunkett, McTiernan 23 and Singh's deposition transcripts? 24 A I didn't know who the other experts 25 were, so I didn't ask for them by name. And I</p>

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<p>1 think that I asked if they could share with me</p> <p>2 transcripts of depositions and reports. So I also</p> <p>3 had some of the reports from those experts. I'm</p> <p>4 not sure I had all of them but at least some of</p> <p>5 them.</p> <p>6 Q Well, what materials had you reviewed</p> <p>7 with respect to other experts in the MDL before</p> <p>8 you completed your report that we've marked as</p> <p>9 Exhibit 10?</p> <p>10 A None. All of what I've just described</p> <p>11 was after I completed my report.</p> <p>12 Q Did you rely on the work or opinions of</p> <p>13 any other expert witnesses in forming your own</p> <p>14 opinions in the MDL?</p> <p>15 A No, I don't think I did.</p> <p>16 Q So understanding that more depositions</p> <p>17 have been taken than just Drs. Plunkett, McTiernan</p> <p>18 and Singh, what specifically was your request to</p> <p>19 plaintiffs' counsel for which deposition</p> <p>20 transcripts you would like to see?</p> <p>21 MS. PARFITT: Objection. Asked and</p> <p>22 answered, form.</p> <p>23 THE WITNESS: I'm not sure if my request</p> <p>24 was to see the ones that they thought were most</p> <p>25 relevant to -- to me or whether I specifically</p>	<p>1 I specifically asked at some point to be provided</p> <p>2 with information that would inform on the presence</p> <p>3 of asbestos fibers in talcum powder products.</p> <p>4 BY MS. BRANSCOME:</p> <p>5 Q Did you review that material before</p> <p>6 completing your MDL report?</p> <p>7 MS. PARFITT: Do you understand the</p> <p>8 question?</p> <p>9 THE WITNESS: Yeah.</p> <p>10 Yes, I think I did look at that before</p> <p>11 completing my report.</p> <p>12 BY MS. BRANSCOME:</p> <p>13 Q When you say the asbestos is an issue</p> <p>14 that has come up in the last few months, what do</p> <p>15 you mean by that?</p> <p>16 A Well, my understanding back in 2016,</p> <p>17 '17, was that while asbestos had been detected in</p> <p>18 talcum powder products as far back as the '70s --</p> <p>19 1970s, there was an industry directive or promise</p> <p>20 or instruction that they would somehow get rid of</p> <p>21 the problem of asbestos contamination.</p> <p>22 Q And what was your basis for that</p> <p>23 understanding?</p> <p>24 A I guess things I've read, and possibly</p> <p>25 in some of the company documents, possibly in</p>
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<p>1 said the epidemiology ones, but I think probably</p> <p>2 the former, because they sent me, for example,</p> <p>3 Dr. Plunkett, who is not an epidemiologist. Yeah.</p> <p>4 BY MS. BRANSCOME:</p> <p>5 Q Which expert reports have you reviewed</p> <p>6 that are from the MDL?</p> <p>7 A I looked at the Plunkett report. I</p> <p>8 think I looked at the Singh and the McTiernan</p> <p>9 report. But just dipping into it, not -- not</p> <p>10 reading it fully. Yeah.</p> <p>11 Q Any other reports?</p> <p>12 A Not that I recall offhand.</p> <p>13 Q Okay. The Blount transcript, the</p> <p>14 Hopkins transcript, and the table from Julie</p> <p>15 Pier's deposition, were those items that were</p> <p>16 provided to you by plaintiffs' counsel?</p> <p>17 A Yes.</p> <p>18 Q Did you request them specifically or</p> <p>19 were they simply given to you?</p> <p>20 MS. PARFITT: Objection. Form.</p> <p>21 THE WITNESS: I requested them to</p> <p>22 provide me with information that would help me to</p> <p>23 understand the issue. And one of the issues that</p> <p>24 has come up in the past few months was the issue</p> <p>25 of asbestos in talcum powder products, and I think</p>	<p>1 publications. I think there have been various</p> <p>2 publications that have said so that have -- and I</p> <p>3 can't right now point to those, but that for the</p> <p>4 last 10 or 20 years have said that asbestos</p> <p>5 contamination may have been a problem up to the</p> <p>6 1970s, but that the industry has basically managed</p> <p>7 to eliminate that contamination. So I've read</p> <p>8 that, and it seemed to be repeated often enough</p> <p>9 that I came to take it as a fact.</p> <p>10 And then I received some -- I guess I</p> <p>11 received some reports from plaintiffs' counsel of</p> <p>12 some new studies carried out more recently in</p> <p>13 the -- by Longo and his team, and some others, put</p> <p>14 in question whether asbestos fibers were present</p> <p>15 in talcum powder products. And so this caused me</p> <p>16 to revisit that whole thing.</p> <p>17 My opinions offered in 2016, '17, about</p> <p>18 talc and ovarian cancer were premised on the</p> <p>19 assumption that whereas there may have been some</p> <p>20 contamination up to the 1970s, it was basically a</p> <p>21 nonissue after the 1970s. So the opinions I</p> <p>22 expressed in -- in 2016, '17, were independent of</p> <p>23 any hypotheses about asbestos in talc.</p> <p>24 When I saw the reports from Longo and</p> <p>25 maybe others in the fall -- I think it was in the</p>

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<p style="text-align: right;">Page 98</p> <p>1 fall of 2018, I specifically asked counsel to 2 provide me with other information that they had, 3 and I made a point of saying, you know, Are there 4 studies that contradict these -- is there evidence 5 that contradicts these evidence -- these claims of 6 asbestos contamination? And they sent me some 7 material at that point. 8 Q Okay. The work that Dr. Longo had 9 conducted with respect to analyzing talcum powder 10 products, to your knowledge, has that ever been 11 published? 12 A I'm not sure. I -- to my knowledge, no, 13 but maybe it has been. I don't know. 14 Q Okay. What were you -- when you 15 referred to the study that Dr. Longo conducted, 16 what -- are you referring to the work that he has 17 done in connection with litigation on behalf of 18 plaintiffs' counsel? 19 A I'm referring to a few reports that I 20 think are dated or -- not -- 2017, 2018. I guess 21 they're connected to litigation, but I'm -- I'm 22 not absolutely certain of that. But those are -- 23 that's what I'm referring to. 24 Q Separate and apart from your role as an 25 expert witness, when you're evaluating a</p>	<p style="text-align: right;">Page 100</p> <p>1 of the investigators. I know many of the people 2 in the area that I work in, and I can -- often 3 have a gut feeling about the quality of their 4 work. 5 Q Do you know anything about Dr. Longo's 6 qualifications such that you could render an 7 opinion about the quality of his work? 8 A It's in a different area than mine, so 9 the answer is I -- I couldn't render an opinion 10 about it. 11 Q When you asked for evidence that might 12 contradict the work that Dr. Longo had done in 13 connection with litigation, what specifically were 14 you provided by plaintiffs' counsel? 15 A I'm sorry, without digging around and 16 looking at e-mail exchanges, offhand I can't tell 17 you. I was provided with a batch of -- of 18 documents. I can't remember how many were on one 19 side or the other side. I remember there -- well, 20 in my report I refer to a few pieces of evidence 21 that -- yes. So -- can I -- well, on page 30 in 22 my copy -- 23 Q Okay. 24 MS. PARFITT: Why don't you give the 25 category, the title.</p>
<p style="text-align: right;">Page 99</p> <p>1 scientific question, do you typically consult 2 expert reports that are generated for purposes of 3 litigation? 4 MS. PARFITT: Objection. Form. 5 THE WITNESS: I would -- if I had 6 access -- I mean, usually we don't know about such 7 reports if we're not in the litigation process. 8 So it's a hypothetical question, I guess. It -- 9 it just doesn't come up in reality that I would be 10 looking at carcinogenicity of diesel engine 11 emissions, and I would have access to reports 12 produced in litigation that are not published. 13 I -- I don't know that I -- I wouldn't have access 14 to such information unless I was part of the 15 litigation. But... 16 BY MS. BRANSCOME: 17 Q Okay. When you're evaluating scientific 18 literature, do you place a different amount of 19 weight on a study that has been peer reviewed as 20 compared to one that has not? 21 A Yes, it's one of the considerations. 22 Q Okay. And -- 23 A There -- there are many considerations 24 that I weigh, including my knowledge of and 25 evaluation of the skill and reputation and quality</p>	<p style="text-align: right;">Page 101</p> <p>1 THE WITNESS: Oh, the -- so it's in 2 Section 5.3.2, "What were women exposed to in body 3 powders?" 4 BY MS. BRANSCOME: 5 Q Were you provided, for example, with the 6 expert reports generated by the expert retained by 7 Johnson & Johnson and Imerys to rebut Dr. Longo's 8 report? 9 A Can you give me the author's name or -- 10 Q Sure. Were you provided any reports by 11 Dr. Matthew Sanchez? 12 A I don't recall. I don't recall that. 13 Q Are you offering an expert opinion about 14 the contents of any of the talcum powder products 15 sold or manufactured by Johnson & Johnson? 16 A I only take note of what has been 17 provided in the various documents I have access 18 to. 19 Q What does that mean? 20 A It means -- can I read the sentence? 21 Basically, I think it summarizes what I mean. And 22 I'll start -- so I'll start on the sentence that 23 on my copy is on the bottom of page 29, still in 24 that Section 5.3.2. 25 "So representatives of the industry have</p>

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<p>1 claimed that talcum powders were free of asbestos</p> <p>2 fibers since the 1980s" -- and there are a couple</p> <p>3 of references there --</p> <p>4 MS. PARFITT: Read them.</p> <p>5 THE WITNESS: "Hopkins 2018, Pier 2018.</p> <p>6 -- "but this assertion has increasingly</p> <p>7 come under doubt as a number of labs have reported</p> <p>8 finding asbestos fibers in talcum powder</p> <p>9 products." And it references Blount, '91;</p> <p>10 Paoletti, '84; Gordon, 2014; Longo, et al., 2017</p> <p>11 and 2018; Blount deposition, 2018; Pier</p> <p>12 deposition, 2018.</p> <p>13 "These various studies that have</p> <p>14 reported finding asbestos in historic talcum</p> <p>15 powder samples have been challenged by other</p> <p>16 reports that failed to find meaningful amounts of</p> <p>17 asbestos in historic talcum powder samples." And</p> <p>18 the two citations are CIR 2013 and Anderson 2017.</p> <p>19 BY MS. BRANSCOME:</p> <p>20 Q So what I'm trying to understand,</p> <p>21 Dr. Siemiatycki, is what role this information</p> <p>22 plays in your opinions, if any.</p> <p>23 A Not much. You know, I would say that</p> <p>24 the -- my opinions about the association are</p> <p>25 driven by the strength and consistency of the</p>	<p>1 and answered.</p> <p>2 THE WITNESS: You know, I would say the</p> <p>3 sentences that I read summarize my opinion on that</p> <p>4 question.</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q So in your opinion, is it -- is it a</p> <p>7 question for debate in the scientific community at</p> <p>8 the moment?</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 Misstates his testimony.</p> <p>11 THE WITNESS: It's not an area in which</p> <p>12 I feel confident to pronounce that the issue has</p> <p>13 been resolved or not.</p> <p>14 MS. BRANSCOME: Is now a good time for a</p> <p>15 break? I don't now how long --</p> <p>16 MR. TISI: We've been going about an</p> <p>17 hour and 25 minutes.</p> <p>18 MS. PARFITT: We have lunch at 1:00, and</p> <p>19 I don't think it's here.</p> <p>20 (A discussion was held off the record.)</p> <p>21 MS. BRANSCOME: We can go off the</p> <p>22 record.</p> <p>23 THE VIDEOGRAPHER: This ends disc number</p> <p>24 in the deposition of Jack Siemiatycki. We're</p> <p>25 going off the record at 12:42 p.m.</p>
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<p>1 epidemiologic evidence. And this information</p> <p>2 about asbestos contamination of talcum powder</p> <p>3 products would be capable of moving the dial in</p> <p>4 the direction of increasing my belief that there</p> <p>5 is a causal assoc- -- a causal relationship, if it</p> <p>6 is demonstrated that there were in fact asbestos</p> <p>7 fibers contaminating.</p> <p>8 So if it is shown that they are present,</p> <p>9 that would increase my level of belief. If it is</p> <p>10 not shown, if it is not demonstrated, it would not</p> <p>11 detract from my finding based on the epidemiologic</p> <p>12 evidence. It could move the dial in one</p> <p>13 direction. It wouldn't move the dial in another,</p> <p>14 because there -- there are different conceivable</p> <p>15 ways that talcum powder products could increase</p> <p>16 the risk of ovarian cancer. This is one. I'm not</p> <p>17 capable of adjudicating whether this one is</p> <p>18 correct or not.</p> <p>19 Q So as you sit here today,</p> <p>20 Dr. Siemiatycki, do you have an opinion to a</p> <p>21 reasonable degree of scientific certainty that</p> <p>22 there are in fact contaminants like asbestos or</p> <p>23 heavy metals in Johnson & Johnson's talcum powder</p> <p>24 products?</p> <p>25 MS. PARFITT: Objection. Form. Asked</p>	<p>1 (Lunch recess.)</p> <p>2 THE VIDEOGRAPHER: This begins disc</p> <p>3 number 3 in the deposition of Jack Siemiatycki.</p> <p>4 We're going back on the record at 1:46 p.m.</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q Good afternoon, Dr. Siemiatycki.</p> <p>7 Did you have a chance to look at the</p> <p>8 various subjects we were going to return to after</p> <p>9 the lunch break?</p> <p>10 A I did.</p> <p>11 Q Okay. So we'll take them one at a time.</p> <p>12 A Yes, please.</p> <p>13 Q Let's start first with, did you identify</p> <p>14 the document that you had been provided by</p> <p>15 plaintiffs' counsel that you said you took out all</p> <p>16 but about 20 pages that you found relevant?</p> <p>17 A Right. So I -- I think I mentioned the</p> <p>18 IARC monographs as being two of them, and I think</p> <p>19 the third one was the Reference Manual on</p> <p>20 Scientific Evidence. There was a huge pack of</p> <p>21 pages that were sent to me, and I took out most of</p> <p>22 them, but I retained some that I thought were</p> <p>23 relevant.</p> <p>24 Q What portions of the Reference Manual on</p> <p>25 Scientific Evidence did you retain?</p>

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<p>1 A I think it was the Epidemiology section</p> <p>2 and maybe the Statistics section.</p> <p>3 Q All right. During the break, you were</p> <p>4 also going to check which of the epidemiological</p> <p>5 studies that you included in your meta-analysis.</p> <p>6 Did you or someone at your direction</p> <p>7 independently calculate an odds ratio or relative</p> <p>8 risk figure that was not published in the report</p> <p>9 itself?</p> <p>10 A Sorry, what? That was not published in</p> <p>11 the original report. So I'm not sure. The answer</p> <p>12 is in the time I had available, I couldn't really</p> <p>13 identify anything like that, and I'm not sure if</p> <p>14 that occurred at all, and it -- the impact of</p> <p>15 that, if -- if it had occurred, would have been</p> <p>16 negligible.</p> <p>17 Q If --</p> <p>18 A It would have meant -- I'm sorry. It</p> <p>19 would have meant that most likely I added -- I put</p> <p>20 together a two-by-two table by aggregating across</p> <p>21 two or three or four levels of exposure. If -- if</p> <p>22 it had happened, I think that's what would have</p> <p>23 happened. And the impact of that would be to</p> <p>24 produce an odds ratio estimate that is not</p> <p>25 adjusted for the covariates that they adjusted for</p>	<p>1 think what it is, we've got the signature page on</p> <p>2 the one report, and then the one he has in his</p> <p>3 binder appears to not have a signature page on it,</p> <p>4 and the font seems to be -- when the signature</p> <p>5 page was put in, the font was slightly larger,</p> <p>6 which sort of throws off the page numbers. Same</p> <p>7 report.</p> <p>8 MS. BRANSCOME: So what I would --</p> <p>9 MS. PARFITT: Single --</p> <p>10 MS. BRANSCOME: -- request so that we</p> <p>11 keep the record clean going forward and not every</p> <p>12 question has to say page 108 in mine and page 107</p> <p>13 in your copy is that we actually mark the version</p> <p>14 of the report that has been produced to us as</p> <p>15 Exhibit 11 -- well, let me just, Ms. Parfitt,</p> <p>16 would you be comfortable marking his copy as</p> <p>17 Exhibit 11 and switching them and putting the new</p> <p>18 clean copy as Exhibit 10? I'm only thinking that</p> <p>19 there are many prior questions --</p> <p>20 MS. PARFITT: Sure, I'm fine with that.</p> <p>21 MS. BRANSCOME: -- that refer to his</p> <p>22 report --</p> <p>23 MS. PARFITT: As long as his --</p> <p>24 MS. BRANSCOME: -- as Exhibit 10.</p> <p>25 MS. PARFITT: Yeah, and just so the</p>
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<p>1 in their analysis by the categories of dose or</p> <p>2 whatever they adjusted for.</p> <p>3 Q Is there any way by examining your 2018</p> <p>4 report and the addendum that an outside reader</p> <p>5 could determine which studies, if any, were</p> <p>6 subject to this independent calculation?</p> <p>7 A So the one thing I didn't check during</p> <p>8 the break was whether there's a note in the</p> <p>9 addendum, and it would take me a while, I'd have</p> <p>10 to go through each study and see if there's any</p> <p>11 notation in the margin that would indicate that</p> <p>12 this was done. So I -- I -- I'm not sure of the</p> <p>13 answer to your question.</p> <p>14 Q If an adjustment like that or an</p> <p>15 independent calculation had been done, would it be</p> <p>16 your expectation that a notation would have been</p> <p>17 made in the addendum?</p> <p>18 A Yes. Yes.</p> <p>19 Q All right. Did you look at anything</p> <p>20 else over the lunch break?</p> <p>21 A Well, we looked to see -- the page --</p> <p>22 pagination discrepancy between the different</p> <p>23 versions, and I think Ms. Parfitt could fill you</p> <p>24 in on -- or maybe she has. I don't know.</p> <p>25 MS. PARFITT: No. No, I haven't. I</p>	<p>1 record is clear, and what appears to have happened</p> <p>2 is there was a signature page that was put on the</p> <p>3 report to represent the matter was filed in the</p> <p>4 United States District Court, the District of New</p> <p>5 Jersey, in light of the prior report that was in a</p> <p>6 state court, and that has thrown off not only the</p> <p>7 page numbers but I think even it might have been a</p> <p>8 different font.</p> <p>9 Sure, so we will put on --</p> <p>10 THE WITNESS: So do you want to modify</p> <p>11 the -- this?</p> <p>12 MS. PARFITT: Sure. I think what we're</p> <p>13 going to do is the one that Dr. Siemiatycki has</p> <p>14 brought will be now Exhibit 11, and the one that's</p> <p>15 in -- on the thumb drive and --</p> <p>16 MS. BRANSCOME: It is tab 3 in the</p> <p>17 binder in front of you will be the correct</p> <p>18 Exhibit 10.</p> <p>19 MS. PARFITT: And this will be</p> <p>20 Exhibit 11.</p> <p>21 MR. TISI: And Exhibit 11 will be his</p> <p>22 copy, the one that he brought.</p> <p>23 MS. PARFITT: And this will be 3 -- 3,</p> <p>24 correct?</p> <p>25 MS. BRANSCOME: 11 -- I mean 10. It's</p>

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<p style="text-align: right;">Page 110</p> <p>1 tab 3.</p> <p>2 MS. PARFITT: 11 -- 10. Tab 3, correct.</p> <p>3 (Exhibit No. 11 was marked for</p> <p>4 identification.)</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q So, Dr. Siemiatycki, can you confirm</p> <p>7 that Exhibit 10 is a complete copy of your report</p> <p>8 that was submitted in the MDL? It is a clean copy</p> <p>9 and does not contain any annotations.</p> <p>10 A Yes.</p> <p>11 Q Can you also confirm that what we have</p> <p>12 now marked as Exhibit 11 is the copy of your MDL</p> <p>13 report that you brought with you here today? It</p> <p>14 does contain handwritten annotations and the page</p> <p>15 numbers are just slightly misaligned.</p> <p>16 A Yes.</p> <p>17 Q Okay. So if you could, in Exhibit --</p> <p>18 oh, there was one other --</p> <p>19 A There was one other, and -- and there's</p> <p>20 another -- yet another one that I -- a correction</p> <p>21 to be made, a small one.</p> <p>22 So do you want to point out what that --</p> <p>23 Q Yes. So, Dr. Siemiatycki, do you have</p> <p>24 any corrections that you would like to make to</p> <p>25 your report at this time?</p>	<p style="text-align: right;">Page 112</p> <p>1 would like to make at this time?</p> <p>2 A Yes. I'd like to make one -- oh, yes.</p> <p>3 Well, page 72 in this version.</p> <p>4 MS. PARFITT: Just refer to the exhibit</p> <p>5 number, so 11.</p> <p>6 THE WITNESS: Exhibit 11, page 72,</p> <p>7 Table 2. Table 2 of the report.</p> <p>8 BY MS. BRANSCOME:</p> <p>9 Q What is the correction you would like to</p> <p>10 make?</p> <p>11 A The correction is -- there's a column</p> <p>12 called "Included in main meta-analysis," and I</p> <p>13 think in your copy, as in mine in this version,</p> <p>14 there are a bunch of question marks. In the</p> <p>15 original Word document that I submitted, these</p> <p>16 were not question marks. They were tick marks,</p> <p>17 checkmarks. And somehow in the translation of</p> <p>18 Word to PDF, this -- the tick mark -- the tick</p> <p>19 marks got changed to these funny little question</p> <p>20 marks. So they should all be tick marks.</p> <p>21 Q Are there any other corrections you</p> <p>22 would like to make to your report?</p> <p>23 A Not that I'm aware of at this time.</p> <p>24 Q Okay. So if you could turn to</p> <p>25 Exhibit 10 -- which is in front of you there -- if</p>
<p style="text-align: right;">Page 111</p> <p>1 A So the one outstanding one that we had</p> <p>2 highlighted -- or we've gone through the three of</p> <p>3 them.</p> <p>4 MS. PARFITT: 45.</p> <p>5 THE WITNESS: Have we --</p> <p>6 MS. PARFITT: No, 45. Page --</p> <p>7 MR. TISI: No, 47. 45.</p> <p>8 MS. PARFITT: Page 45. Excuse me, it's</p> <p>9 47.</p> <p>10 THE WITNESS: Oh, yes, that -- the</p> <p>11 question of whether that sentence should refer to</p> <p>12 Berge or Terry on that page. It's Berge 2018, not</p> <p>13 Terry. I was right the first time.</p> <p>14 MS. PARFITT: Oh, and it is page 45,</p> <p>15 just for the record. It is not 47. That was the</p> <p>16 first correction is on page 45.</p> <p>17 THE WITNESS: In this version.</p> <p>18 BY MS. BRANSCOME:</p> <p>19 Q So just to be clear, Dr. Siemiatycki, on</p> <p>20 the third line of page 45 of Exhibit 10, the</p> <p>21 reference to Terry 2013 in the sentence beginning</p> <p>22 with the word "while" should in fact be Berge</p> <p>23 2018?</p> <p>24 A Yes.</p> <p>25 Q Do you have any other corrections you</p>	<p style="text-align: right;">Page 113</p> <p>1 you could turn to your Conclusion section. It</p> <p>2 should be on page 69.</p> <p>3 A Yes.</p> <p>4 Q You state in the second paragraph below</p> <p>5 the Conclusion section that: "Based on the</p> <p>6 totality of the evidence, it is my opinion to a</p> <p>7 reasonable degree of scientific certainty that the</p> <p>8 perineal use of talcum powder products can cause</p> <p>9 ovarian cancer."</p> <p>10 First, did I read that correctly?</p> <p>11 A Yes, you did.</p> <p>12 Q Does that conclusion accurately</p> <p>13 summarize your opinion in this case as to whether</p> <p>14 or not perineal use of talcum powder can cause</p> <p>15 ovarian cancer?</p> <p>16 A Yes, it does.</p> <p>17 Q You state that your opinion is to a</p> <p>18 reasonable degree of scientific certainty,</p> <p>19 correct?</p> <p>20 A Correct.</p> <p>21 Q Is that a phrase that you have ever used</p> <p>22 in a scientific publication?</p> <p>23 A I don't think so.</p> <p>24 Q Why did you use it here?</p> <p>25 A I've seen this phrase used in all of the</p>

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<p style="text-align: right;">Page 114</p> <p>1 expert opinions in the legal cases that I've seen, 2 and I inferred that it's a -- a formula that is 3 de rigueur in legal communications for this sort 4 of thing. 5 Q When you say "to a reasonable degree of 6 scientific certainty," what do you mean by that 7 phrase? 8 A So my -- you know, I think somewhere 9 else in the document, I -- I phrase it in a way 10 that I'm comfortable with, which is a way that 11 also is sort of derivative from my understanding 12 of legal jargon and precedence. I think that it's 13 more likely than not that there is a causal 14 relationship. 15 Q You anticipated where I was going with 16 my question. Do those two sentences mean anything 17 different to you? 18 A No. 19 Q What is your understanding of "more 20 likely than not"? 21 A From a strictly mathematical point of 22 view, it implies that I feel that there's greater 23 than 50 percent probability that this thesis is 24 true. And I wouldn't put a more quantitative 25 meaning onto it.</p>	<p style="text-align: right;">Page 116</p> <p>1 that exists today enable a scientist to parse that 2 out? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I'm not sure I understand 5 the premise of the question, the "if" part. 6 BY MS. BRANSCOME: 7 Q Okay. So if the biological mechanism by 8 which a talcum powder product can cause ovarian 9 cancer is because of a particular contaminant in 10 that talcum powder product, but that contaminant 11 does not exist in all talcum powder products, 12 would the epidemiological evidence that exists 13 today allow you to see that distinction? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: The epidemiologic evidence 16 as -- as it exists today would not allow one to 17 parse out anything about the particular 18 manufacturer, the particular product, if I 19 understand your question correctly. 20 BY MS. BRANSCOME: 21 Q And so therefore, the epidemiological 22 evidence as it exists today does not have a level 23 of detail by which someone reviewing that data 24 could determine if there were different 25 contaminants present in different talcum powder</p>
<p style="text-align: right;">Page 115</p> <p>1 Q Is your opinion that perineal use of 2 talcum powder products can cause ovarian cancer, 3 is it specific to a single brand or manufacturer 4 of talcum powder? 5 A No, it isn't. 6 Q Why not? 7 A Because as I understand it, the 8 epidemiologic evidence that supports the thesis of 9 a causal relationship is derived from evidence 10 among women who used all types of talcum powder 11 products that were available in their consumer 12 area of purchase of these products. And whatever 13 was the frequency distribution of different 14 manufacturers and types of powdering that were 15 available in the consumer -- various consumer 16 markets were the types that lead to the overall 17 inference about causality, and there's no way for 18 me to parse out which particular manufacturer 19 would have been more or less responsible for any 20 of this. 21 Q If in fact, and we're just talking 22 hypothetically, the biological mechanism by which 23 some talcum powder products can cause ovarian 24 cancer is related to a contaminant in that talcum 25 powder product, does the epidemiological evidence</p>	<p style="text-align: right;">Page 117</p> <p>1 products that were used by individuals who 2 developed ovarian cancer -- 3 MS. PARFITT: Objection. Form. 4 BY MS. BRANSCOME: 5 Q -- correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: May I read the -- 8 MS. PARFITT: Yes, you can. 9 BY MS. BRANSCOME: 10 Q Of course. 11 A Just to make sure I understand. 12 (Peruses document.) 13 So I -- I don't think that the 14 epidemiological evidence would allow you to 15 attribute causality to a specific type or -- or 16 not. If one knew -- if part of your hypothetical 17 is the knowledge of what the constituents were of 18 different products used in different markets, and 19 the biological mechanism has been established to a 20 high degree of certainty, there might be some room 21 for making inferences about this. But that seems 22 like a tenuous possibility. 23 Q But you agree that the current 24 epidemiological evidence as it exists does not 25 enable someone to distinguish between brands of</p>

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<p style="text-align: right;">Page 118</p> <p>1 cosmetic talc products, for example? 2 MS. PARFITT: Objection. Form. 3 THE WITNESS: I don't think it does. 4 BY MS. BRANSCOME: 5 Q Does -- is your opinion that perineal 6 use of talcum powder products can cause ovarian 7 cancer, is that limited to talcum powder products 8 manufactured during a certain time period? 9 A The evidence as it exists today pertains 10 to products manufactured over half a century, 11 roughly speaking, so I don't think that there's 12 any way to link it to products manufactured in a 13 particular time period. 14 In -- in answer to that question, 15 actually, and to the previous one, hypothetically, 16 one might imagine looking at the different 17 study -- the 30-odd studies that have been carried 18 out in different communities and different cities 19 and different countries, and if one could obtain 20 reliable, reasonably precise and time relevant 21 information on market shares of products in 22 different markets at different times, that could 23 give a first approximation of whether certain 24 company products are more closely linked to the 25 excesses that are seen in the epidemiological</p>	<p style="text-align: right;">Page 120</p> <p>1 ovarian cancer in that area, it would be 2 improbable that the product of that company were 3 not part of the responsibility, but one of the 4 companies that produced 5 or 10 percent of the 5 market share. 6 BY MS. BRANSCOME: 7 Q Okay. But as you sit here today, based 8 on the analysis that you have done, you are not 9 able to draw an opinion specifically about an 10 increased risk of ovarian cancer that is tied to a 11 particular brand or a particular time period, 12 correct? 13 MS. PARFITT: Objection. Form. 14 THE WITNESS: That's correct, in part 15 because I don't have data on market share at 16 different times and in different places. 17 BY MS. BRANSCOME: 18 Q Okay. In forming your opinion that 19 perineal talc use can cause ovarian cancer, did 20 you reach an opinion about how much talcum powder 21 is needed to cause ovarian cancer? 22 A No. 23 Q Is there an amount of talcum powder that 24 can be used perineally without increasing a risk 25 for ovarian cancer?</p>
<p style="text-align: right;">Page 119</p> <p>1 studies. 2 Q The application, though, of a market 3 share analysis to the users of talcum powder 4 products, if you're looking at causality, would 5 require that the individuals who developed ovarian 6 cancer had purchased their talcum powder according 7 to the market share, correct? 8 MS. PARFITT: Objection. Form. 9 THE WITNESS: Approximately, yes. 10 BY MS. BRANSCOME: 11 Q So, for example, if one type of talcum 12 powder product or one time period of talcum powder 13 product is the only type that actually causes 14 ovarian cancer, so all of the positives were 15 derived from those users, you -- you could not 16 determine that simply by applying market share, 17 for example? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: That -- that's true, 20 except in the circumstance that market share were 21 very, very high in most of the communities that 22 have been investigated. So if one company 23 produced 90 percent or 85 percent or something of 24 the product in a certain area -- that was consumed 25 in a certain area, and there's an excess risk of</p>	<p style="text-align: right;">Page 121</p> <p>1 A So let me go back to the previous 2 question, and clarify what do you mean by amount? 3 Do you mean like the amount in grams? The amount 4 in number of applications? The amount in number 5 of day -- days on which the powder is applied? 6 These are all different metrics of exposure, and 7 the answer might depend on what kind of -- you 8 know, we're starting with these studies. There 9 are now some hints about the dose-response 10 relationship and what kind of levels of exposure 11 in terms of number of applications in use, 12 observable excess risks. 13 Q So let me ask it this way: Did you 14 calculate how much talcum powder is needed to 15 cause ovarian cancer in any of the forms, be it 16 frequency of application, the amount in grams that 17 was used? 18 A I -- 19 MS. PARFITT: Objection. Form. 20 THE WITNESS: I did not carry out such a 21 calculation. I'm -- my emphasis was on 22 determining whether there's a dose-response 23 relationship. Going beyond that might involve 24 trying to quantify the dose-response relationship 25 to the extent of determining what the shape of</p>

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<p style="text-align: right;">Page 122</p> <p>1 such a relationship is and how the curve looks, 2 whether there's a threshold effect, and so on. 3 But I don't think there's enough data now to be 4 able to make such estimates. 5 BY MS. BRANSCOME: 6 Q Can you rule out the possibility that 7 there is a threshold below which perineal use of 8 talc presents no risk of ovary -- of ovarian 9 cancer? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: No, I -- I don't think -- 12 I can't, and I don't think it's possible to do 13 that with most carcinogens. It's -- it's an 14 extremely difficult and controversial issue of how 15 to detect sort of a minimum level of exposure 16 produces a carcinogenic effect. 17 BY MS. BRANSCOME: 18 Q In your view, has a dose-response 19 relationship for the perineal application of talc 20 and the development of ovarian cancer been 21 established in the scientific literature? 22 A My view is that the data are certainly 23 compatible with the notion of a dose-response 24 relationship. It -- it trends in that direction 25 of that conclusion. It's not definitive yet.</p>	<p style="text-align: right;">Page 124</p> <p>1 ovarian cancer, is that the question? Almost. 2 But the one qualification I would make in 3 answering that question is that I have a colleague 4 who started working with -- in my academic 5 department about 12 years ago, and she was 6 interested in ovarian cancer as a topic of 7 research, and she wanted to organize a case- 8 control study of ovarian cancer in relation to 9 various factors, and she asked me to kind of 10 mentor her -- she was just starting out -- mentor 11 her in getting grants, in setting up the study, 12 and this sort of thing, and this is what I did 13 with her. 14 So I worked on grant applications with 15 her on some aspects of setting up her study, and 16 that has been going on now for -- I don't know -- 17 I think since 2010 maybe that she started. So -- 18 but that has not -- I've been what we call a 19 coinvestigator on that project, not a principal 20 investigator. 21 But apart from that, the next stage in 22 my involvement with talc and ovarian cancer was in 23 the litigation. 24 Q What is your colleague's name? 25 A Anita Koushik.</p>
<p style="text-align: right;">Page 123</p> <p>1 It's not definitive. But I believe the bulk of 2 the evidence, especially from the Terry study and 3 partly from, I think it's the, Schildkraut study, 4 which are the most powerful ones for that 5 question, but certainly the Terry study is by far 6 the most important one, does tend to indicate 7 dose-response relationship. 8 Q Is the data that exists today also 9 compatible with no dose-response relationship? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: Yes. It could be -- in 12 other words, it could be a chance finding. Is -- 13 that's what you're saying. I think it's unlikely, 14 but it's -- it can't be ruled out. 15 BY MS. BRANSCOME: 16 Q Are you offering an expert opinion that 17 the inhalation of talc increases or presents any 18 risk of ovarian cancer? 19 A I -- I don't have an opinion on -- on 20 that. No. 21 Q Aside from your participation in the 22 IARC panel in 2006 and the Langseth article on 23 2008, has all of your work on talc and ovarian 24 cancer been in connection with litigation? 25 A On talc and -- sorry, work on talc and</p>	<p style="text-align: right;">Page 125</p> <p>1 Q If you had to give me your best 2 estimate, how many hours total have you spent 3 assisting her with the case-control study? 4 MS. PARFITT: Objection. Form, 5 misstates his testimony. 6 THE WITNESS: It's very hard to answer 7 that. I mean, ten years ago discussions over 8 coffee about studies and how to write grant 9 applications and reviewing and revising and so on. 10 I -- I don't -- not a trivial amount and not an 11 overwhelming amount. 12 BY MS. BRANSCOME: 13 Q When was the last time that you spent 14 hours in connection with that case-control study? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: There was a manuscript 17 that came -- a publication that came from that 18 study. It was -- the study was only completed in 19 the field, the data collection, around two years 20 ago, and spending a year cleaning data and so on, 21 and then starting to analyze it. 22 And there was an analysis of 23 reproductive and hormonal factors in relation to 24 ovarian cancer, and I helped her review and revise 25 that manuscript. That would have been a year and</p>

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<p>1 a half ago or so, and I don't know, maybe I spent 2 three or four days on it at the time. 3 BY MS. BRANSCOME: 4 Q Did that study reach any conclusions 5 with respect to a potential link between perineal 6 use of talc and ovarian cancer? 7 A The talc information was collected in 8 the questionnaire and has not yet been analyzed. 9 Q Other than what we just discussed with 10 respect to the case-control study and then your 11 work in connection with the IARC panel and the 12 Langseth paper, have you ever done any original 13 research on the association between perineal 14 talcum powder use and ovarian cancer? 15 A No. No, I haven't. 16 It's common -- it's common for me to be 17 asked to review information on which I have not 18 directly worked. You know, topics. You know, I 19 recently was asked by the government of France to 20 evaluate a problem of possible cancer risks 21 related to a pesticide that's used in the banana 22 industry in Guadeloupe and Martinique. I've never 23 studied that pesticide and I've never been to 24 Martinique. But the kind of expertise that I have 25 can be applied to studying different sorts of</p>	<p>1 A That's correct. 2 Q Have you done anything since 2016 to 3 publicly announce your view that the perineal use 4 of talc can cause ovarian cancer? 5 A No, I've not had really an opportunity. 6 And in a way the -- the publication by Berge, 7 which appeared as a -- after I completed my 8 meta-analyses, and they -- they kind of beat me to 9 the punch with one type of publication output that 10 I might have produced. So I'm thinking about 11 different ways of communicating my results and my 12 opinions, but mainly my results. 13 I mean, the other part of the answer 14 to -- another part of the answer to your question 15 is that I'm not particularly a fan of individual 16 scientists going into press with opinions before 17 some sort of consensus starts to appear. I mean, 18 you can -- you can publish hypotheses and ideas, 19 but proclaiming conclusions is something that 20 should come later in the scientific process. I 21 mean, I -- I think it's best if IARC or an agency 22 like IARC would take on that role, and that would 23 be my hope actually. 24 Q In your opinion, has consensus formed 25 that peri- -- perineal use of talc can cause</p>
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<p>1 problems. 2 Q You have not published the meta-analyses 3 that you -- meta-analysis you performed in 4 connection with the MDL, have you? 5 A No, I haven't. 6 Q Have you ever published in any peer- 7 reviewed article the opinion that the perineal use 8 of talcum powder can cause ovarian cancer? 9 A I -- I've never had occasion to opine 10 about this in any publication, and one doesn't 11 just announce to the New England Journal of 12 Medicine that you want to, you know, write an 13 article about opining about something like this. 14 There has to be some sort of platform basis of 15 research evaluation and so on. 16 And my involvement in this case might 17 lead to such a publication, but in the past I 18 would have not -- I had no reason to publish or to 19 try to publish such an opinion. 20 Q But you had formed an opinion with 21 respect to the perineal use of talcum powder and 22 an increased risk of ovarian cancer at the time 23 that you published your report in October of 2016. 24 And by "published," I mean within the 25 litigation context, correct?</p>	<p>1 ovarian cancer? 2 A I think among people who have reviewed 3 the evidence who -- sort of competent scientists 4 who have reviewed the evidence, I think there's 5 starting to be a ground swell of consensus about 6 it. You know, I've never done a survey, so I 7 can't say if it's majority or minority. 8 If your denominator is all medical 9 researchers, then the answer is, well, most of 10 them have never heard of this issue, so it's 11 not -- they wouldn't be susceptible to holding 12 such an opinion. But among the people who have 13 reviewed, are familiar with the issues, I think 14 there's certainly a much higher level of 15 receptivity to this thesis than there was ten 16 years ago. 17 Q Has a consensus been reached that 18 perineal use of talc probably causes ovarian 19 cancer? 20 MS. PARFITT: Objection. Asked and 21 answered. Form. 22 THE WITNESS: I can't answer that 23 question. I -- it's too -- are you trying to make 24 the distinction between probably and -- I -- so -- 25 BY MS. BRANSCOME:</p>

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<p>1 Q Well, what do you understand the phrase 2 "can cause ovarian cancer" to mean? 3 A Well, it's a synonym with "is a risk 4 factor for" or -- that's how I understand it. 5 Q All right. And is that in your mind the 6 same as "it probably causes cancer"? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: "It probably can cause," 9 is that what you said, or "probably does cause"? 10 BY MS. BRANSCOME: 11 Q Probably does cause. 12 A So I don't think any risk factor can be 13 described as -- in a way with the wording "does 14 cause." You know, smoking does not cause lung 15 cancer. It can cause lung cancer when there's a 16 constellation of other favorable circumstances. 17 You know, this is part of multifactorial causation 18 of disease. So, you know, each factor in itself 19 is not the cause, but it's part of a constellation 20 of factors that together can cause the disease. 21 So each of them can cause the disease. 22 Q So -- you -- you state in your report 23 that -- let me see if I can get the exact 24 language. 25 And perhaps you can get me there more</p>	<p>1 THE WITNESS: I don't know -- I haven't 2 carried out a survey among people. I don't know 3 whether a consensus has been reached. I don't 4 know what proportion of that community would 5 subscribe to this point of view or not. 6 BY MS. BRANSCOME: 7 Q Okay. Setting aside conducting a survey 8 of individuals in the scientific community, would 9 you say that the scientific literature reflects a 10 consensus that the causal relationship between 11 perineal talc powder exposure and ovarian cancer 12 is probable? 13 MS. PARFITT: Objection. Form. 14 THE WITNESS: I think the scientific 15 literature supports that conclusion. I'm not sure 16 that it reflects it. 17 So there's kind of a lag period between 18 the production of research findings and the 19 consensus -- a consensus building around it and 20 being expressed in print. You know, if we take 21 sort of the classic smoking and lung cancer 22 historical example, evidence was accumulating 23 rapidly in the 1950s. There were several studies 24 through the 1950s and early 1960s, and it was only 25 in 1964, so many years after some of this evidence</p>
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<p>1 quickly. You talk about that now you would give a 2 different rating under the IARC standard. 3 Ah, here we go. Page 67 in your 2018 4 report. You state: "It is now my professional 5 opinion based on the totality of the evidence, 6 that to a reasonable degree of scientific 7 certainty, the causal relationship between 8 perineal talc powder exposure and ovarian cancer 9 is," quote, "probable." 10 Did I read that correctly? 11 A You did. 12 Q Do you hold that opinion? 13 A Yes, I do. 14 Q What do you mean when you say a "causal 15 relationship between perineal talc powder exposure 16 and ovarian cancer is," quote, "probable"? 17 A I mean it's more likely than not. 18 Q Okay. Has a consensus been reached in 19 the scientific community, understanding we're 20 looking at those who have an interest in this 21 issue, been reached that the causal relationship 22 between perineal talc powder and ovarian cancer is 23 probable? 24 MS. PARFITT: Objection. Form, asked 25 and answered.</p>	<p>1 had been published and been accepted by many 2 scientists, but rejected by others -- there was 3 still controversy around it -- that the Surgeon 4 General's report reflected and created a 5 consensus. 6 BY MS. BRANSCOME: 7 Q So in early 2019, are we still in the 8 lag period or the period in which the production 9 of research findings is still behind consensus 10 building in the literature? 11 MS. PARFITT: Objection. Form, 12 misstates his testimony. 13 THE WITNESS: Does that mean I should 14 answer or -- 15 MS. PARFITT: I'm objecting. I said it 16 misstates your prior testimony. 17 THE WITNESS: Okay. Sorry. Let me read 18 the question again. (Peruses monitor.) 19 So I can't point to hallmark 20 publications analogous to the Surgeon General's 21 report for smoking and lung cancer that would 22 reflect such a bend in the road kind of general 23 perception of the talc ovarian cancer issue. It 24 doesn't mean that the evidence isn't there, but 25 the process of recognizing and generalizing and so</p>

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<p>1 on is not -- has not been achieved yet.</p> <p>2 BY MS. BRANSCOME:</p> <p>3 Q Okay. Have you ever given a lecture,</p> <p>4 either to students or to other scientists, in</p> <p>5 which you have presented your view that the</p> <p>6 perineal use of talcum powder can cause ovarian</p> <p>7 cancer?</p> <p>8 A I have to my students -- I mean to the</p> <p>9 students in my department. I teach epidemiologic</p> <p>10 methods. I don't teach about ovarian cancer. I</p> <p>11 don't teach about talc. That's not what I'm paid</p> <p>12 to do. I'm paid to teach about the methodology</p> <p>13 and the conduct of -- and the interpretation of</p> <p>14 epidemiologic -- and I've used the talc/ovarian</p> <p>15 cancer as an example and walked my students</p> <p>16 through the evidence. So, yes, I have.</p> <p>17 Q When did you start teaching that as part</p> <p>18 of your epidemiological methods course?</p> <p>19 A Probably two years ago. As soon as I</p> <p>20 started gathering the information and synthesizing</p> <p>21 it, so two -- two or three years ago.</p> <p>22 Q Other than presenting to your students</p> <p>23 your analysis of talc and ovarian cancer as an</p> <p>24 illustration of an epidemiological method, have</p> <p>25 you presented your opinion that perineal use of</p>	<p>1 think. (Peruses document.)</p> <p>2 Q Okay.</p> <p>3 A No, I've never spoken to any of them</p> <p>4 about -- I -- I crossed paths with Dr. Cramer in</p> <p>5 Los Angeles for a -- you know, we were in the same</p> <p>6 hotel. He was leaving, I was coming, that sort of</p> <p>7 thing, but I don't think we had any substantive</p> <p>8 discussion, and I can't -- I know some of the</p> <p>9 others, but I've never spoken to them about this</p> <p>10 issue.</p> <p>11 Q Do you know personally or professionally</p> <p>12 any of the other plaintiffs' experts in the MDL?</p> <p>13 A No, I don't.</p> <p>14 Q You were chair of the working group --</p> <p>15 the IARC Working Group that published the</p> <p>16 monograph on talc in 2006 -- or, well, that met in</p> <p>17 2006, and then was subsequently published in 2010,</p> <p>18 correct?</p> <p>19 A That's correct.</p> <p>20 Q And there were roughly 20 members of</p> <p>21 that working group?</p> <p>22 A I think so.</p> <p>23 Q In 2006, you agreed with the IARC</p> <p>24 classification of, quote, "possible" describing</p> <p>25 the relationship between perineal talc use and</p>
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<p>1 talcum powder can cause ovarian cancer in any</p> <p>2 other context outside of litigation?</p> <p>3 A No, I haven't.</p> <p>4 Q Have you spoken with other scientists</p> <p>5 about the issue of whether perineal use of talcum</p> <p>6 powder can cause ovarian cancer? Setting aside</p> <p>7 your students.</p> <p>8 A Yeah. Yes, I've spoken to -- to</p> <p>9 colleagues, friends over -- over coffee, over</p> <p>10 drinks at conferences, you know, what are you up</p> <p>11 to, what are you doing, and then describe my</p> <p>12 involvement in this case. And then we dig a</p> <p>13 little further into, Well, what -- what do you</p> <p>14 think, and so on. So I -- I have discussed it in</p> <p>15 that kind of format.</p> <p>16 Q Have you ever spoken with any of the</p> <p>17 authors on any of the papers that you cite in your</p> <p>18 report about the potential link between perineal</p> <p>19 use of talc and ovarian cancer?</p> <p>20 A I don't think so. I can quickly scroll</p> <p>21 through the list to see if anything jogs my --</p> <p>22 yeah -- no, let me --</p> <p>23 Q If you can do that quickly, we could do</p> <p>24 it now, or we can save that for the next break.</p> <p>25 A It will take just three minutes, I</p>	<p>1 ovarian cancer, correct?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: That's correct. I could</p> <p>4 read the exact wording of what "to be" means, but</p> <p>5 that's the gist of it.</p> <p>6 BY MS. BRANSCOME:</p> <p>7 Q Okay. IARC has not changed its</p> <p>8 clarification of talc, and specifically with</p> <p>9 respect to the peri- -- perineal use of talc since</p> <p>10 it published the 2010 monograph, correct?</p> <p>11 A Technically correct, but actually,</p> <p>12 what -- the correct statement is IARC has not</p> <p>13 evaluated talc since 2006 -- has not reevaluated.</p> <p>14 So there are no changes made to IARC evaluations</p> <p>15 except through a formal complete reevaluation, and</p> <p>16 there has not been a formal complete reevaluation</p> <p>17 of talc since the 2006 meeting. So there's no</p> <p>18 opportunity for IARC to change anything in one</p> <p>19 direction or another failing another complete</p> <p>20 evaluation.</p> <p>21 Q What, if you know, can initiate a formal</p> <p>22 complete evaluation of a constituent like talc?</p> <p>23 A Well, it comes I think from different</p> <p>24 sources. I'm not entirely certain. I know that</p> <p>25 there is now a public process whereby public</p>

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<p>1 parties can write to the monograph program and</p> <p>2 make suggestions for chemicals to be evaluated.</p> <p>3 There are -- they get requests from governments.</p> <p>4 They get requests from groups of scientists. They</p> <p>5 have their own internal scientific staff that has</p> <p>6 its antenna out for different problems that arise,</p> <p>7 and they generally have sort of a five-year</p> <p>8 program of agents that they are going to evaluate</p> <p>9 in every -- in the next five-year period.</p> <p>10 These things are not quick and easy to</p> <p>11 organize, and so there's a lot of lead time.</p> <p>12 There's a lot of, in a way, competition for agents</p> <p>13 to get onto the list to be evaluated. There are a</p> <p>14 lot of interested parties that would like the</p> <p>15 agent that they are exposed to or the "et cetera"</p> <p>16 to be evaluated. So the exact mechanics of how</p> <p>17 they make decisions, I haven't been involved in</p> <p>18 that process, but that's, roughly speaking, how</p> <p>19 it's done.</p> <p>20 Q Have you ever submitted a request to</p> <p>21 IARC for them to conduct a complete evaluation of</p> <p>22 talc?</p> <p>23 A Have I ever?</p> <p>24 Q Have you since the publication of the</p> <p>25 monograph in 2010 submitted a request to IARC for</p>	<p>1 sentence -- you know, in the context of a</p> <p>2 conversation about many things, as we do when we</p> <p>3 catch up when we meet. What -- you know, what's</p> <p>4 on the agenda for the monograph program? By the</p> <p>5 way, I think talc might be an interesting thing to</p> <p>6 put on a list for you to consider. And probably</p> <p>7 the conversation ended -- that part of the</p> <p>8 conversation ended and moved on to other things.</p> <p>9 But...</p> <p>10 MR. KLATT: Should we take a break?</p> <p>11 MS. BRANSCOME: I understand the noise,</p> <p>12 but I -- I don't know that Dr. Siemiatycki was</p> <p>13 finished with his answer.</p> <p>14 MS. PARFITT: We'll keep going. I</p> <p>15 didn't -- I was trying to keep a clean record for</p> <p>16 you. That's fine. Keep going.</p> <p>17 MS. BRANSCOME: Well, we -- we can</p> <p>18 pause. I just was trying to let him finish his</p> <p>19 answer.</p> <p>20 MS. PARFITT: We'll keep it paused here</p> <p>21 on the screen. Just a little bit more activity.</p> <p>22 THE VIDEOGRAPHER: We will pause for a</p> <p>23 second. We're going off the record, 2:41 a.m. --</p> <p>24 p.m.</p> <p>25 (Pause.)</p>
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<p>1 them to conduct another complete evaluation of</p> <p>2 talc?</p> <p>3 A I had a quick word with the director of</p> <p>4 the monograph program a few months ago, and I</p> <p>5 suggested it might be time for that. But I'm</p> <p>6 intending to submit a more formal request along</p> <p>7 those lines. So...</p> <p>8 Q Okay. Who -- who specifically did you</p> <p>9 speak with a few months ago?</p> <p>10 A The director of the monograph program is</p> <p>11 Kurt Straif, S-T-R-A-I-F.</p> <p>12 Q And how did you have occasion to be</p> <p>13 speaking with the director?</p> <p>14 A We're acquaintances, and I met him at a</p> <p>15 conference in August, I saw him when I was in Lyon</p> <p>16 in November at a meeting that he organized. So</p> <p>17 I've seen him a few times in the last six months.</p> <p>18 Q When did you have this conversation with</p> <p>19 the director?</p> <p>20 A I think it was in the summer.</p> <p>21 Q So the summer of 2018?</p> <p>22 A Yeah.</p> <p>23 Q And what specifically did you discuss</p> <p>24 with him?</p> <p>25 A I -- I think it might have been a one</p>	<p>1 THE VIDEOGRAPHER: We're going back on</p> <p>2 the record at 2:43 p.m.</p> <p>3 BY MS. BRANSCOME:</p> <p>4 Q When you spoke with the director of the</p> <p>5 monograph program for IARC last summer, did you</p> <p>6 inform him that you have been serving as an expert</p> <p>7 witness on behalf of plaintiffs in litigation</p> <p>8 involving talcum powder products and the claim</p> <p>9 that they cause ovarian cancer?</p> <p>10 A I'm not sure if I told him at that time,</p> <p>11 but I certainly have told him since then.</p> <p>12 Q When you were talking to him about the</p> <p>13 possibility of including talc in a formal,</p> <p>14 complete evaluation subsequent to the one that was</p> <p>15 done in 2006 and published in 2010, did you tell</p> <p>16 him anything about your opinions with respect to</p> <p>17 the likelihood that perineal use of talc can cause</p> <p>18 ovarian cancer?</p> <p>19 A I don't think I did.</p> <p>20 Q What did he say about -- if anything,</p> <p>21 about conducting a formal evaluation of talc?</p> <p>22 A I -- I can't remember if he said</p> <p>23 anything about it.</p> <p>24 Q Have you had any conversations with him</p> <p>25 other than the conversation you had last summer</p>

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<p>1 about IARC conducting another examination of talc</p> <p>2 and its potential carcino- -- carcinogenicity --</p> <p>3 whoops, butchered that one -- about it's ability</p> <p>4 to cause cancer?</p> <p>5 A No. I don't think I did.</p> <p>6 Q Now, you said you have an -- you have</p> <p>7 the intention to submit something formal to IARC;</p> <p>8 is that correct?</p> <p>9 A Yes. I've been thinking about it, and</p> <p>10 I -- when I have time, I'll look into the process.</p> <p>11 Q What specifically would you request that</p> <p>12 IARC do at this time with respect to talc?</p> <p>13 A Carry out an evaluation like they did in</p> <p>14 2006 but with up-to-date data.</p> <p>15 Q What data specifically do you think an</p> <p>16 IARC Working Group would need to consider that was</p> <p>17 not available in 2006? What are the key pieces of</p> <p>18 data that you think should be considered by a</p> <p>19 working group?</p> <p>20 A So from an epidemiological database</p> <p>21 point of view, there have been a number of</p> <p>22 publications, as you know, since 2006, including</p> <p>23 some cohort studies, various case-control studies,</p> <p>24 various meta-analyses, a pooled analysis from the</p> <p>25 Terry group. All of that information bears on the</p>	<p>1 sufficient growth in the information base that</p> <p>2 would justify it. And the question is whether</p> <p>3 there are other priorities -- that they have</p> <p>4 things with even higher priorities for them to</p> <p>5 look at.</p> <p>6 Q We agree the perineal use of talc</p> <p>7 currently is classified by IARC as a Group 2B</p> <p>8 chemical, correct?</p> <p>9 A Correct.</p> <p>10 Q So the classification or the definition</p> <p>11 of a Group 2A chemical still applies when there is</p> <p>12 limited evidence of carcinogenicity in humans and</p> <p>13 then sufficient evidence of carcinogenicity in</p> <p>14 experimental animals, correct?</p> <p>15 A Yes.</p> <p>16 Q Has there been developments in the</p> <p>17 experimental animal data since the IARC Working</p> <p>18 Group evaluated the risks associated with the</p> <p>19 perineal use of talc in 2006?</p> <p>20 A I'm not aware whether there has been.</p> <p>21 I -- it does not spring to mind. I can't think of</p> <p>22 any examples.</p> <p>23 Q Now, I noticed in your report you have a</p> <p>24 description, it's on page 24, of the different</p> <p>25 categories that IARC might rate a chemical.</p>
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<p>1 evaluation of cancer risk. It -- it may or may</p> <p>2 not change the view of a working group vis-à-vis</p> <p>3 the view held by the 2006 working group, but</p> <p>4 there's enough new information there that it could</p> <p>5 potentially change points of view.</p> <p>6 And in the mechanism area, I understand</p> <p>7 that there has been additional work on various</p> <p>8 possible areas of -- concerning the migration of</p> <p>9 particles around the body and how this might</p> <p>10 influence the -- the biological plausibility of</p> <p>11 such a -- a process. The possible role, roles of</p> <p>12 inflammation or oxidative stress. There have been</p> <p>13 developments -- there are new publications in</p> <p>14 those areas that might influence a new working</p> <p>15 group or a working group looking at it with new</p> <p>16 eyes.</p> <p>17 For all of those reasons, I think it</p> <p>18 would be timely, and in any case, if a decision</p> <p>19 were made today to do this, such a meeting would</p> <p>20 probably not be held before 2022 or 2023 at the</p> <p>21 earliest. They have a horizon of priorities that</p> <p>22 they're working on. So -- and by then, there</p> <p>23 would likely be additional work that would be</p> <p>24 available.</p> <p>25 So it's an area where I think there is</p>	<p>1 Do you see where I am?</p> <p>2 A Yes, I see where you are.</p> <p>3 Q Okay. And there's a rating system that</p> <p>4 IARC uses that ranges from 1 to 4, correct?</p> <p>5 A Yes.</p> <p>6 Q That -- you have indicated here on</p> <p>7 page 24 on your report that number 4 is not a</p> <p>8 carcinogen. Is that accurate? Is that an</p> <p>9 accurate description of category 4?</p> <p>10 A The wording is longer than that, but</p> <p>11 this is my potted version of what that longer</p> <p>12 version means.</p> <p>13 Q The actual definition is that it is</p> <p>14 probably not carcinogenic, correct?</p> <p>15 A Correct.</p> <p>16 MS. BRANSCOME: Would now be a good time</p> <p>17 for a break?</p> <p>18 MS. PARFITT: I think so. We can take a</p> <p>19 break. Thank you.</p> <p>20 THE VIDEOGRAPHER: We are going off the</p> <p>21 record at 2:51 p.m.</p> <p>22 (Recess.)</p> <p>23 THE VIDEOGRAPHER: This is the beginning</p> <p>24 disc number 4 in the deposition of Jack</p> <p>25 Siemiatycki. We're going back on the record at</p>

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<p style="text-align: right;">Page 146</p> <p>1 3:27 p.m. 2 BY MS. BRANSCOME: 3 Q Good afternoon, again, Dr. Siemiatycki. 4 A Hi. 5 Q Do you still agree with the IARC 6 characterization that the case-control studies 7 evaluating a potential connection between perineal 8 talc powder exposure and ovarian cancer are 9 unusually consistent? 10 A Unusually -- they're very consistent. 11 I'm not sure I would choose the word "unusually." 12 Sometimes when 20 people write a document, 13 everyone doesn't agree with every word, but they 14 are very consistent. 15 Q Do you agree with the IARC determination 16 that the excess in risk in those case-control 17 studies is, quote, modest? 18 A That the what, the increase in risk? 19 Q Or the excess of risk. 20 A Yeah, the -- I mean, the terminology 21 around strength of association -- weak, modest, 22 strong, very strong, medium, et cetera -- it 23 doesn't have -- there are no regulations. There's 24 no epidemiologic handbook that says if a relative 25 risk is in this range, you call it weak or</p>	<p style="text-align: right;">Page 148</p> <p>1 this -- there are not many that have such high 2 relative risks. 3 I'm just giving you a bit of background 4 because the terminology is controversial, and I 5 know it plays into the case of how we -- how we 6 characterize the associations around talc and 7 ovarian cancer. 8 There are a lot of associations that are 9 much less than -- with relative risks much lower 10 than ten that are very well accepted as being 11 causal associations. And so the idea that 12 associations have to be, quote/un- -- quote, 13 strong in the sense that the smoking-lung cancer 14 association was strong is not really tenable any 15 more. There are so many -- most known carcinogens 16 don't have such strong -- don't have such high 17 relative risks. So where you draw the line 18 between strong, moderate, weak, and so on, is a 19 kind of -- is a vague notion. 20 If you're asking me how I would 21 characterize it or how it's characterized -- I'm 22 not sure whether you want to go -- to ask how I 23 would characterize it or how it's characterized by 24 other people or -- 25 Q So, respectfully, Dr. Siemiatycki, my</p>
<p style="text-align: right;">Page 147</p> <p>1 moderate and so on and so forth. 2 So the term "moderate" -- actually, the 3 terminology around strength of associations was 4 probably most influenced by the smoking and lung 5 cancer situation in the '50s and '60s where there 6 were relative risks of ten approximately, ten 7 times as high of risk for smokers as for 8 nonsmokers of getting lung cancer, and that was 9 considered a benchmark for strong associations. 10 And it was not known then whether most carcinogens 11 would fall -- most carcinogens that would be 12 discovered later than that era would fall into the 13 category, you know, of relative risks, around ten 14 or around five or around two or whatever. 15 So the -- the use of the terms "strong," 16 "medium," "weak" has kind of been -- what's the 17 word? -- benchmarked, I guess, by the smoking-lung 18 cancer association. And things that -- 19 subsequently relative risks that were less than in 20 that order of magnitude of ten or so where people 21 didn't refer to them as strong because they were 22 not as strong as smoking and lung cancer. 23 It has subsequently turned out that the 24 level of relative risk for smoking and lung cancer 25 is exceptional among known carcinogens, and that</p>	<p style="text-align: right;">Page 149</p> <p>1 question was, do you agree with the IARC 2 classification of the increase in risk as, quote, 3 modest? 4 A So there was no such classification. It 5 was a word used in a sentence, I guess. There 6 is -- they never classified the association as 7 being strong, weak, moderate or whatever. It was 8 part of a narrative about the -- the body of 9 evidence. 10 Do I agree that -- yeah, I would use 11 that term today. 12 I'm sorry if I digressed from your 13 question. 14 Q You would agree that the point estimate 15 of the meta-analysis that you conducted in 2018 16 that's contained in your report marked Exhibit 10 17 is actually lower than the point estimate that was 18 reported in the Langseth 2008 study, correct? 19 A That's correct. 20 Q And the Langseth 2008 paper, the 21 meta-analysis that you and your coauthors 22 conducted resulted in a 1.35 relative risk, 23 correct? 24 A That's correct. 25 Q And in Exhibit 10, your report in the</p>

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<p style="text-align: right;">Page 150</p> <p>1 MDL, the relative risk point for your 2018 2 meta-analysis is 1.28, correct? 3 A In the 2018 -- yes, that's correct. 4 Q Is it your opinion -- well, let me just 5 ask you, what classification should perineal use 6 of talc get with respect to ovarian cancer under 7 the IARC scale? 8 MS. PARFITT: Objection. Form. 9 THE WITNESS: I -- I'm very reluctant to 10 answer that question because it takes a lot of 11 input from different disciplines to produce an 12 IARC evaluation and then IARC classification. And 13 I feel it's presumptuous for any one person from 14 one discipline to take on that function. 15 What I can say is that in this 16 situation, the epidemiologic evidence alone is 17 sufficient to make the -- make me think that it's 18 more likely than not that there is a causal 19 association. How that proposition would feed into 20 an IARC evaluation is something that would -- that 21 a multidisciplinary group would need to work out, 22 but I think there's at least enough evidence to 23 say it's more likely than not. 24 BY MS. BRANSCOME: 25 Q Because you would agree that a work --</p>	<p style="text-align: right;">Page 152</p> <p>1 causality, but it's not a one-to-one kind of 2 relationship. 3 Now I've lost the thread. I'm sorry. 4 BY MS. BRANSCOME: 5 Q That's okay. I'm going to ask you the 6 question again. 7 Simply the fact that the epidemiological 8 evidence -- 9 A Yeah. 10 Q -- may support a conclusion that more 11 likely than not perineal talc use can cause 12 ovarian cancer, that fact alone is not sufficient 13 to result in a Group 2A classification of a 14 chemical under IARC. 15 MS. PARFITT: Objection. Form. 16 BY MS. BRANSCOME: 17 Q Is that fair? 18 A It's fair -- in principle, it's a fair 19 statement. My feeling is that if that occurred in 20 a meeting, and if -- you know, in an IARC Working 21 Group, the group is subdivided into four 22 subgroups: Initially, an epidemiology group, 23 animal experimentation group, other biological 24 mechanisms, and then expose -- an exposure group. 25 If the epidemiology group came back, had</p>
<p style="text-align: right;">Page 151</p> <p>1 an IARC Working Group, for example, if a former -- 2 formal evaluation was done on talc, in order to 3 classify talc as say a Group 2A, that working 4 group would need to consider multiple lines of 5 evidence, correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: That's correct. 8 BY MS. BRANSCOME: 9 Q And simply the determination, if it were 10 the case that the epidemiological evidence might 11 support the conclusion that perineal use of talc 12 more likely than not can cause ovarian cancer, 13 would not by itself be sufficient for a Group 2A 14 rating. Is that fair? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: The IARC classification 17 was developed in the 1970s. It was not developed 18 in order to fit into a template that can be used 19 in the courtroom. So terms like "more likely than 20 not" or, you know, whatever terminology would be 21 used in a courtroom around this sort of thing does 22 not fit perfectly on the IARC classification 23 scale. 24 I understand why courts use IARC 25 evaluations as an input to understanding</p>	<p style="text-align: right;">Page 153</p> <p>1 a feeling that there likely -- it was more likely 2 than not that there is a causal association, they 3 have the prerogative to categorize the evidence as 4 being sufficient or limited. And it's not clear 5 how they would categorize the epidemiologic 6 evidence. That would feed into the final 7 evaluation. 8 Q So you would say, as you sit here today, 9 based on what you know about the epidemiological 10 evidence with respect to the perineal use of talc 11 and ovarian cancer, it's not clear whether that 12 would satisfy the criteria for sufficient evidence 13 of carcinogenicity. Is that fair? 14 MS. PARFITT: Objection. Misstates his 15 testimony. 16 THE WITNESS: For -- for a particular 17 working group. Because the other particularity of 18 the IARC process, as with other -- from high level 19 scientific processes, is that it depends a lot on 20 scientific judgment. There's -- there are 21 guidelines for how to combine animal evidence and 22 basic biology evidence in epidemiology, but all of 23 these guidelines are just models of how the final 24 evaluation might be determined. 25 Each working group is sovereign and can</p>

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<p>1 take the entire body of evidence and make a 2 decision outside the -- the template -- the -- the 3 typical template. So a working group could look 4 at the evidence and decide is it Group 1, it's 5 Group 2B, Group 2A, based on the totality of 6 evidence. 7 In general, if the epidemiology is 8 convincing, it would be Group 1 or Group 2A if 9 it's convincing but not -- or let's say if it's -- 10 if it indicates a risk but it's not definitive. 11 BY MS. BRANSCOME: 12 Q So you would say if the epidemiology 13 indicates a risk but is not definitive, you think 14 there's a possibility a chemical would be 15 classified as Group 1? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: It depends how close to 18 definitive it is. So if the feeling of the group 19 is that it's almost certain on the basis of 20 epidemiologic evidence, then they could classify 21 it as Group 1, and they would classify the 22 epidemiologic evidence as sufficient in that case. 23 BY MS. BRANSCOME: 24 Q Okay. On the scale of definitiveness, 25 where would you place the evidence of the perineal</p>	<p>1 (A discussion was held off the record.) 2 BY MS. BRANSCOME: 3 Q Do you remember what you were answering 4 or should we -- 5 A I prefer if -- I'm sorry. If you could 6 ask again and -- 7 Q Let me ask it a different way. Is it 8 possible for a confounding variable to essentially 9 infect all of the epidemiology on a particular -- 10 looking at a particular causal relationship? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: It is possible. 13 BY MS. BRANSCOME: 14 Q Okay. If that were to happen and you 15 see evidence in the epidemiology that shows a 16 consistent increase in risk but there's the 17 potential for a confounding variable, would it be 18 important to look at the potential biological 19 mechanism to see whether or not the agent might be 20 causing the outcome? 21 A So the confounding factor is -- is a 22 factor that could be captured in epidemiologic 23 studies but hasn't been. Is that what you are 24 alluding to? And the biologic -- but the biologic 25 mechanism that you're referring to would involve</p>
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<p>1 use of talc and ovarian cancer as of today? 2 A Based on the epidemiologic evidence. 3 Q Correct. 4 A I -- I go back to more likely than not. 5 Not -- not definite, but more likely than not. 6 Q Is it possible to have a situation where 7 the epidemiological evidence is supportive of a 8 causal association, but the group working on 9 biological mechanism determines that there isn't a 10 sufficient mechanism by which that chemical could 11 have caused that outcome? 12 A That can happen. 13 Q And what would the explanation for an 14 inconsistency like that be? 15 A It would require quite a high level of 16 understanding of the mechanistic evidence. 17 So -- I -- I don't know if it has 18 happened, so I'm -- I'm trying to think through 19 memory whether I can think of any examples. I'm 20 not sure that it has happened. 21 THE VIDEOGRAPHER: Excuse me, Counsel. 22 The microphone just fell. 23 THE WITNESS: Oh, I'm sorry. 24 MS. BRANSCOME: That's okay. You just 25 knocked off your microphone.</p>	<p>1 that confounding factor or is this -- are you -- 2 are you confounding "confounding" with -- with 3 biologic mechanism issues? 4 Q Okay. Let me -- let me give you a 5 specific hypothetical. 6 A Yes. 7 Q Okay. So let's say hypothetically, for 8 example, recall bias -- 9 A Okay. 10 Q -- affects the epidemiology related to 11 looking at the causal relationship, and whether 12 you agree with it or not, but we'll just say 13 hypothetically that affected the epidemiology of 14 talc use and ovarian cancer. 15 A Can I just interrupt for a 16 terminological thing? So typically we don't refer 17 to recall bias as a confounding factor. 18 Q Ah. 19 A We refer to it as a bias, a type of 20 bias, but -- you know, that's just technical, but 21 for the record, if we're going to be discussing 22 this further. 23 Q I appreciate the clarification. 24 A Thank you. 25 Q Well, first of all, let me just ask you,</p>

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<p style="text-align: right;">Page 158</p> <p>1 is recall bias something that could affect the 2 reliability of conclusions drawn from 3 epidemiological studies that rely on recall to 4 define exposure to the agent? 5 A Yes, it could, hypothetically. 6 Q Okay. Is recall bias something that 7 potentially could affect the epidemiological 8 studies of the perineal use of talc? 9 A Yes, theoretically, it could. 10 Q Okay. In situations where there is a 11 potential bias or a confounding variable that has 12 not been identified, how should epidemiological 13 evidence be evaluated in comparison to the other 14 categories of evidence that are considered, for 15 example, by an IARC Working Group? 16 A Well, these things would typically be 17 evaluated in a -- a nonquantitative way. You 18 can't really quantify what is the potential impact 19 of a confounder that you don't know about or that 20 you haven't measured. It's kind of a theoretical 21 thing. 22 And the same with -- with recall bias 23 where there could be some evidence about it. And 24 certainly when I reviewed the evidence on this 25 topic, the possibility of recall bias was one of</p>	<p style="text-align: right;">Page 160</p> <p>1 exposures, all -- you know, environmental things 2 that they've been exposed to, et cetera, there -- 3 there's no reason why exposure to talc would be 4 the one item in epidemiologic questionnaires that 5 would provoke recall bias where nothing else does. 6 So if it's a part of a general 7 phenomenon, this recall bias, which is certainly a 8 hypothetical possibility, we would see that most 9 of the associations that were tested in case- 10 control studies would be found to be high risks, 11 maybe significantly high risks. 12 That's not what we observed. That's not 13 what I've observed in my research. I have 14 estimated -- and in the book that I showed this 15 morning, there are literally thousands of odds 16 ratio estimates in there. But in all of my 17 research on over nearly four decades, I've 18 published a lot of evidence, and I can show some 19 examples, where there's no difference between 20 cases and controls because there is no effect, 21 there's no causal association between the two 22 things, and the case -- although people were -- 23 cases were asked about, let's say, alcohol 24 consumption, and controls were asked about alcohol 25 consumptions, the cases didn't overreport. They</p>
<p style="text-align: right;">Page 159</p> <p>1 the main stumbling blocks to arriving at an 2 opinion, as it was for the IARC panel in 2006. 3 You know, we are all aware of that hypothetical 4 possibility, and we think about whether something 5 of that magnitude -- something like that could 6 artifactually generate an appearance of a relative 7 risk. 8 My own way of dealing with that was to 9 look at the phenomenon of recall bias from the 10 perspective of both my own research, which has 11 mainly involved case-control studies, some cohort 12 studies but mainly case-control studies, and 13 research that I've read about, experienced, 14 reviewed for journals, et cetera. 15 And if the phenomenon of recall bias 16 were sort of a general across-the-board phenomenon 17 that infects and in a way discredits all 18 case-control studies -- interviewing cases, people 19 who are sick people, interviewing people who are 20 well and comparing the responses -- if this were 21 an inherent systemic problem, what we would 22 observe in general would be a plethora of fake 23 excess risks. Because almost everything you would 24 ask people about, whether it's smoking, alcohol 25 consumption, physical activity, diet, workplace</p>	<p style="text-align: right;">Page 161</p> <p>1 didn't say, Oh, well, they want to know if this 2 caused my cancer, and therefore I'm going to tell 3 them, yes, I consumed a lot of beer and wine and 4 so on, or smoking or whatever. 5 So we don't see this as a general 6 phenomenon that people overreport -- that cases 7 overreport compared to controls. 8 Q Have you looked at the phenomenon of 9 recall bias specifically when the agent being 10 investigated is part of public wide -- wide scale 11 litigation? 12 MS. PARFITT: Object to form. 13 THE WITNESS: So I haven't personally -- 14 let me just think if any of my research has 15 involved situations analogous to that. 16 Yes. Cell phones and brain cancer. So 17 I was involved in a large cell phone and brain 18 cancer study, and we asked cases about their use 19 of cell phones, and we asked controls about their 20 use of cell phones. And while the interpretation 21 of the results of the study were somewhat 22 controversial, there was no generalized phenomenon 23 of cases reporting more cell phone use than 24 controls in that particular study. 25 So that -- I can't think of another</p>

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<p style="text-align: right;">Page 162</p> <p>1 example in my career of sort of one of these 2 generally suspected things. I mean, I've studied 3 a lot of occupational exposures, but those tend to 4 be more obscure, and people don't, you know, have 5 the same visceral reaction maybe to were you 6 exposed to formaldehyde or benzene or this or 7 that. 8 BY MS. BRANSCOME: 9 Q For purposes of your meta-analysis, you 10 looked at the binary question of ever having used 11 talc and never having used talc, correct? 12 A Among other -- not only that, but that 13 in addition to, yeah. 14 Q Yes. For example, you were not -- your 15 data isn't stratified based off of having used it 16 to a certain degree of frequency, correct? 17 A The -- the meta-analysis, no. 18 Q Okay. 19 A I -- I looked at dose-response 20 information within the studies that provided it, 21 but I didn't do any meta-analyses of the -- of the 22 dose-response data. 23 Q Okay. So I -- I asked you sort of the 24 broad question about what has changed in the 25 scientific literature with respect to perineal use</p>	<p style="text-align: right;">Page 164</p> <p>1 A Yeah. 2 Q Are those areas in which you contend 3 there is developments in the scientific literature 4 that is relevant to the question of the connection 5 between perineal use of talc and ovarian cancer? 6 A Yes. 7 Q Okay. So I just wanted to talk to you 8 about which of those categories you are 9 independently offering an expert opinion as 10 opposed to you are deferring to others. Does that 11 make sense? 12 A Yes. 13 Q All right. So you are offering an 14 expert opinion about developments in the 15 epidemiology, correct? 16 A Correct. 17 Q Are you testifying as an expert in 18 developments in the scientific literature with 19 respect to toxicology? 20 A No. 21 Q Are you testifying as an expert with 22 respect to developments in the scientific 23 literature in molecular biology? 24 A No. I -- I'm aware that there have been 25 some publications since 2006 in that domain, but</p>
<p style="text-align: right;">Page 163</p> <p>1 of talc since the 2006 IARC Working Group, but I 2 want to point you now sort of specific to what you 3 say in your report and ask you some more detailed 4 questions about what's changed. 5 So if you could turn to page 67 of 6 Exhibit 10 there. 7 A Yes. 8 Q Sorry, just one moment. My pencil has 9 died on me. Just give me one second. All right. 10 All right. So you have a Section 9 here 11 that says: "Contrast with IARC monograph and 12 other reviews." Do you see that? 13 A I do. 14 Q All right. And you asked the question 15 in your report: "What has changed in the years 16 since the IARC review?" Correct? 17 A Correct. 18 Q All right. And you talk about 19 additional studies and scientific literature 20 addressing a variety of topics, including 21 epidemiology, toxicology, molecular biology and 22 mechanistic studies; is that correct? 23 A Sorry, are -- you're saying that I 24 referred to those domains? 25 Q Yes.</p>	<p style="text-align: right;">Page 165</p> <p>1 I'm not offering an opinion about those. 2 Q Are you offering an opinion with respect 3 to the biological mechanism by which the perineal 4 use of talc may or may not cause ovarian cancer? 5 A Not an opinion. Again, I'm -- I'm 6 acknowledging that there is new evidence, and I 7 mention some of that, yes. 8 Q But as an expert, you're not here to 9 opine on the strengths and weaknesses of that 10 evidence or how it might be weighted against other 11 evidence that's in the field related to biological 12 mechanism; is that fair? 13 MS. PARFITT: Objection. Form. 14 THE WITNESS: That's correct. 15 BY MS. BRANSCOME: 16 Q Okay. Now, you state in your report 17 that: "The various possible biases" -- this is 18 still on page 67 -- "that are on the table remain 19 substantially similar to the ones that were 20 considered by the IARC panel." Correct? 21 A Correct, I said that. 22 Q Okay. What are the various possible 23 biases that you refer to there? 24 A Well, I -- I'd have to go back to the 25 IARC 2006 report to give you a full answer, but I</p>

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<p>1 guess the main things that were highlighted at the</p> <p>2 time were measurement error, how to assess</p> <p>3 exposure to talc, and what the impact of</p> <p>4 measurement error might be on the estimates,</p> <p>5 recall bias and the possible impact that that</p> <p>6 might have.</p> <p>7 Q What do you mean by "measurement error"?</p> <p>8 A Measurement error is closely related to</p> <p>9 recall bias, but it's not the same thing.</p> <p>10 Measurement -- recall bias refers to differences</p> <p>11 between cases and controls in the way they</p> <p>12 respond. Measurement error refers to inaccurate</p> <p>13 recall and reporting, irrespective of whether</p> <p>14 there are cases and controls. There can be</p> <p>15 exactly the same degree of error in -- in recall</p> <p>16 between cases and controls.</p> <p>17 So it's not differential. It's not --</p> <p>18 it's not a recall bias between the two groups.</p> <p>19 But if there's error, if some people report high</p> <p>20 use, and in fact they had medium use and all --</p> <p>21 all this sort of thing, that impacts the estimates</p> <p>22 of relative risk -- even though those errors are</p> <p>23 the same in the cases and controls, that impacts</p> <p>24 the estimates of relative risk, and that generally</p> <p>25 impacts it in the direction of attenuating the</p>	<p>1 there is error in diagnose -- I guess you -- what</p> <p>2 you're alluding to -- let me make sure, you're</p> <p>3 alluding to possible misdiagnosis between</p> <p>4 mesothelioma and ovarian cancer. Is that where</p> <p>5 you're going?</p> <p>6 Q That -- that is one possibility, yes.</p> <p>7 A So in the case of a -- in this situation</p> <p>8 of a cohort study, following up a group of women,</p> <p>9 some of them really get mesotheliomas that are not</p> <p>10 linked to talc exposure, but those women are</p> <p>11 classified as ovarian cancers erroneously.</p> <p>12 They -- that error would have the effect of</p> <p>13 reducing the apparent risk compared to the real</p> <p>14 risk of talc and ovarian cancer. In that context,</p> <p>15 it would have that effect.</p> <p>16 In the context of a case-control study,</p> <p>17 where you start with a group of women who have</p> <p>18 been diagnosed with ovarian cancer but in truth</p> <p>19 some of them had peritoneal mesotheliomas, and you</p> <p>20 compare them to controls, the women who -- and</p> <p>21 assuming that talc has no effect on peritoneal</p> <p>22 mesothelioma, which is another assumption to make,</p> <p>23 but -- but assuming that it does on ovarian</p> <p>24 cancer, just for the sake of argument, lumping in</p> <p>25 the mesotheliomas with the ovarian cancer cases</p>
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<p>1 relative risk estimates, lowering them from what</p> <p>2 they really are.</p> <p>3 So that's one error -- one type of error</p> <p>4 that is -- that permeates epidemiology and that is</p> <p>5 present, and that we have to be conscious of and</p> <p>6 try to evaluate.</p> <p>7 Q Could there be measurement error related</p> <p>8 to misdiagnoses?</p> <p>9 A Yes.</p> <p>10 Q And if there was misdiagnoses in the</p> <p>11 sense that someone was diagnosed with ovarian</p> <p>12 cancer but in fact had a different form of cancer,</p> <p>13 that could actually result in an artificially</p> <p>14 inflated relative risk, correct?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: So that kind of error in</p> <p>17 diagnosis has subtly different meaning in the</p> <p>18 context of a case-control study and a cohort</p> <p>19 study. And if -- if you want, I'll -- I could try</p> <p>20 to answer your question in -- in each context.</p> <p>21 BY MS. BRANSCOME:</p> <p>22 Q Okay.</p> <p>23 A So it has an effect in both contexts,</p> <p>24 but it's a slightly different effect.</p> <p>25 So in the context of a cohort study, if</p>	<p>1 would again create a reduction in the estimate of</p> <p>2 relative risk.</p> <p>3 So in both situations -- I would have to</p> <p>4 work it out on a pad of paper, but I think in both</p> <p>5 cases -- and I did write something about this in</p> <p>6 my report, so if you don't --</p> <p>7 Q Feel free to take a look. Sure.</p> <p>8 A -- mind. Thinking out loud in the</p> <p>9 middle of a deposition is sometimes harder than</p> <p>10 thinking out loud at home. (Peruses document.)</p> <p>11 So I'm looking at page 57,</p> <p>12 Section 7.2.5, at the bottom of the page and then</p> <p>13 going on to the next page, and see if what I said</p> <p>14 then is -- corresponds roughly to what I just</p> <p>15 said.</p> <p>16 I think basically it -- it agrees with</p> <p>17 what I just said. Basically the effect would be</p> <p>18 to attenuate estimates in this situation.</p> <p>19 Q So we discussed -- of the various</p> <p>20 possible biases that might affect the</p> <p>21 epidemiology, we talked about measurement error,</p> <p>22 recall bias, diagnostic error.</p> <p>23 Are there any other potential biases</p> <p>24 that should be considered when evaluating the</p> <p>25 epidemiology on the use of talc peritoneally?</p>

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<p>1 A Yes. So I -- I did list a bunch of</p> <p>2 possible biases in my report. And one of them --</p> <p>3 if you don't mind, I'll just go through the titles</p> <p>4 of the different things that -- starting on</p> <p>5 page 53.</p> <p>6 Bias due to nonresponse or</p> <p>7 nonparticipation. If you carry out a case-control</p> <p>8 study, and you get -- you identify a group of a</p> <p>9 hundred women who are cases, and you ask them to</p> <p>10 participate and only 50 agree to participate, and</p> <p>11 the ones who agree to participate happen to be the</p> <p>12 only ones who used talcum powder, and the other 50</p> <p>13 that you don't know about never used it, that</p> <p>14 would be a problem. And -- but it also depends</p> <p>15 what happens among the controls. Among the</p> <p>16 controls, do you get the same nonresponse bias?</p> <p>17 So there's a -- that is one possible bias in</p> <p>18 case-control studies.</p> <p>19 The second one I listed was recall or</p> <p>20 reporting bias that we've discussed.</p> <p>21 The third one is what I call</p> <p>22 nondifferential or random error, which we</p> <p>23 discussed. It's error in reporting that is equal</p> <p>24 in cases and controls, but it has an impact on</p> <p>25 relative risk estimates.</p>	<p>1 other biases. And this is why I corrected you at</p> <p>2 the beginning when we were talking about</p> <p>3 confounding and bias. I mean it's not -- I'm not</p> <p>4 criticizing you in any way for this. It's --</p> <p>5 there is terminological gray zones in</p> <p>6 epidemiology, so it's not always clear. But --</p> <p>7 Q Would it be fair to describe a</p> <p>8 confounding variable in the context of ovarian</p> <p>9 cancer as something that as of now is unknown that</p> <p>10 makes a particular individual more likely to</p> <p>11 develop ovarian cancer that also, for whatever</p> <p>12 reason, makes them more likely to use talcum</p> <p>13 powder?</p> <p>14 A Yes. That would be a correct</p> <p>15 interpretation of "confounding."</p> <p>16 Q And that is something that should be</p> <p>17 taken into account in evaluating the epidemi- --</p> <p>18 epidemiological literature, correct?</p> <p>19 A That's correct.</p> <p>20 Q And you would agree that the scientific</p> <p>21 community at large has not yet understood all of</p> <p>22 the potential factors that might contribute to a</p> <p>23 susceptibility to develop ovarian cancer, correct?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: Sorry, I -- I was hearing</p>
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<p>1 The fourth one, which we haven't</p> <p>2 discussed, has to do -- it's mainly a problem for</p> <p>3 cohort studies. And if you carry out a cohort</p> <p>4 study of -- focused on cancer, and you collect</p> <p>5 information about exposure, and then follow them</p> <p>6 for two years to find out how many of them got</p> <p>7 cancer, and whether there is a difference between</p> <p>8 the people who were exposed and the people who are</p> <p>9 not exposed, well, that would be pretty hopeless</p> <p>10 because it takes more than two years for cancers</p> <p>11 to develop and be diagnosed. So short follow-up</p> <p>12 periods in cohort studies would be a source of</p> <p>13 bias in cohort studies.</p> <p>14 Diagnostic errors, we've just discussed.</p> <p>15 Initiation of powdering as a result of</p> <p>16 ovarian cancer, is it possible that some women</p> <p>17 who -- that there is a statistical association</p> <p>18 between powdering and ovarian cancer, but it's</p> <p>19 because the women who get ovarian cancer in the</p> <p>20 early stages, to relieve symptoms or to deal with</p> <p>21 discomfort start to use powdering. And so that is</p> <p>22 a potential bias.</p> <p>23 Confounding is the next category, and</p> <p>24 that's -- it's a huge category of potential</p> <p>25 distortion that is a little bit different from the</p>	<p>1 two things with my two ears.</p> <p>2 MS. PARFITT: Sorry.</p> <p>3 THE WITNESS: Can you repeat the last</p> <p>4 part?</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q Yeah. You would agree that all of the</p> <p>7 factors that might make someone susceptible to</p> <p>8 developing ovarian cancer are not currently known.</p> <p>9 A That's correct.</p> <p>10 So are -- are you -- are you getting at</p> <p>11 the potential impact of confounding as -- from</p> <p>12 unknown factors as something that hasn't been</p> <p>13 properly evaluated or that is part of this</p> <p>14 picture?</p> <p>15 Q I am simply asking you --</p> <p>16 A Yes.</p> <p>17 Q -- questions about your opinions.</p> <p>18 A Yes, yeah.</p> <p>19 Q But you agree that the possibility of an</p> <p>20 unknown confounding variable is something that, as</p> <p>21 an epidemiologist, you would at least consider</p> <p>22 when looking at the strength of association</p> <p>23 established by epidemiological studies, correct?</p> <p>24 A I would consider it, and I've considered</p> <p>25 it in the context of this literature, and in my</p>

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<p>1 opinion, it's unlikely that any confounding factor</p> <p>2 or factors would create the pattern of results</p> <p>3 that we see.</p> <p>4 And if I could give you one piece of</p> <p>5 evidence about why I -- you know, that illustrates</p> <p>6 why I think that. A confounding factor can only</p> <p>7 bias the result by a certain amount; not as strong</p> <p>8 as its own relationship to the risk factor.</p> <p>9 So if there's a risk fact- -- if the</p> <p>10 relative risk that we see around 1.3 -- ballpark,</p> <p>11 let's for the sake of argument say 1.3 -- is due</p> <p>12 to a confounding factor, that confounding factor</p> <p>13 would have to have an association with ovarian</p> <p>14 cancer much strong -- stronger than 1.3, but much</p> <p>15 stronger than 1.3.</p> <p>16 And I can -- just to illustrate that, I</p> <p>17 actually have a publication -- I think I gave you</p> <p>18 a copy of that publication of mine that</p> <p>19 illustrates my own research on occupational causes</p> <p>20 of cancer --</p> <p>21 THE VIDEOGRAPHER: Sorry.</p> <p>22 THE WITNESS: Am I again disconnected?</p> <p>23 Okay. When I get excited...</p> <p>24 Yes, that's the one. If I could --</p> <p>25 MS. PARFITT: Make a copy.</p>	<p>1 illustrate the potential impact of confounding in</p> <p>2 this issue of ovarian cancer and talc, and what --</p> <p>3 to explain why I believe that the excess risks</p> <p>4 that we observe are unlikely to be explained by</p> <p>5 confounding.</p> <p>6 Q Okay. You would agree, though, that if</p> <p>7 there was a confounding variable that had a</p> <p>8 relationship with, in this case, ovarian cancer</p> <p>9 that was stronger than 1.3, it could explain an</p> <p>10 increase of 1.3 associated with the use of talc if</p> <p>11 it was similarly connected to the use of talcum</p> <p>12 powder products --</p> <p>13 MS. PARFITT: Objection. Form.</p> <p>14 BY MS. BRANSCOME:</p> <p>15 Q -- correct?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 THE WITNESS: Well, one of the points</p> <p>18 that I want to illustrate is that not only would</p> <p>19 it have to be stronger than 1.3, it would have to</p> <p>20 be a lot stronger than 1.3.</p> <p>21 BY MS. BRANSCOME:</p> <p>22 Q How strong would it need to be?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 THE WITNESS: I'll answer that by -- by</p> <p>25 showing you what -- what we found when we were</p>
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<p>1 THE WITNESS: Do you have any copies?</p> <p>2 MS. PARFITT: I'm looking to see.</p> <p>3 THE WITNESS: So -- well, if I could</p> <p>4 just read a couple of sentences from the abstract</p> <p>5 of this, I'll tell you what this is about. It's</p> <p>6 a study of --</p> <p>7 BY MS. BRANSCOME:</p> <p>8 Q Could you, please, Dr. Siemiatycki,</p> <p>9 identify for me --</p> <p>10 A Oh.</p> <p>11 Q -- what is the paper from which you are</p> <p>12 reading.</p> <p>13 A Yes. This is a paper called "Degree of</p> <p>14 confounding bias related to smoking, ethnic group,</p> <p>15 and socioeconomic status in estimates of the</p> <p>16 associations between occupation and cancer."</p> <p>17 Q Is this something that you cite to or</p> <p>18 reference anywhere in the report that you</p> <p>19 submitted in the MDL?</p> <p>20 A It's only in my CV, which is I think</p> <p>21 part of the record.</p> <p>22 Q What led you to specially identifying</p> <p>23 this article, which you seem to have handy today</p> <p>24 here at the deposition?</p> <p>25 A Because I was thinking about how to</p>	<p>1 examining the associations between different</p> <p>2 occupations and lung cancer.</p> <p>3 So occupation and lung cancer, there are</p> <p>4 some true associations there, as you probably</p> <p>5 know, but -- and we collected information about</p> <p>6 people's occupations. We also collected</p> <p>7 information about their smoking history, their</p> <p>8 socioeconomic status, their ethnicity and so on.</p> <p>9 A lot of factors.</p> <p>10 But the most important part of this was</p> <p>11 looking at the association between lung cancer and</p> <p>12 smoking and -- lung cancer and occupation. We</p> <p>13 chose I think 15 occupations, estimated the odds</p> <p>14 ratios for 15 different associations between</p> <p>15 occupations and lung cancer, and we controlled for</p> <p>16 smoking or we didn't control for smoking. We</p> <p>17 compared the results when you control for smoking</p> <p>18 and when you don't compare -- control for smoking.</p> <p>19 BY MS. BRANSCOME:</p> <p>20 Q Respectfully, Dr. Siemiatycki, I only</p> <p>21 have seven hours to ask you questions.</p> <p>22 A Okay.</p> <p>23 Q Your -- your -- counsel for the</p> <p>24 plaintiffs can ask you to fully explain other</p> <p>25 research that you've done.</p>

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<p style="text-align: right;">Page 178</p> <p>1 A Okay.</p> <p>2 Q It sounds very interesting.</p> <p>3 A Thank you.</p> <p>4 Q But my question to you is, in your</p> <p>5 opinion, how strong would an association have to</p> <p>6 be with a confounding variable in order to play a</p> <p>7 significant role in a 1.3 relative risk?</p> <p>8 A My --</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 THE WITNESS: -- guess, it would have to</p> <p>11 be in the order of 3 to 5. Because it also</p> <p>12 depends on the association between a talc</p> <p>13 powdering behavior and this unknown confounder.</p> <p>14 BY MS. BRANSCOME:</p> <p>15 Q Okay. Are there limitations to</p> <p>16 performing a meta-analysis?</p> <p>17 MR. TISI: Do you want to mark that or</p> <p>18 no?</p> <p>19 MS. BRANSCOME: No.</p> <p>20 THE WITNESS: Are there --</p> <p>21 BY MS. BRANSCOME:</p> <p>22 Q -- limitations to performing a</p> <p>23 meta-analysis?</p> <p>24 A I -- I'm not sure what -- like --</p> <p>25 Q I believe you referenced earlier that</p>	<p style="text-align: right;">Page 180</p> <p>1 In -- one of the differences between --</p> <p>2 as I mentioned earlier, between -- some types of</p> <p>3 meta-analyses are carried out on clinical trials,</p> <p>4 in fact, I would say the bulk of meta-analysis is</p> <p>5 conducted in clinical trials research where the</p> <p>6 research protocols are really very standardized</p> <p>7 from one study to another, and that enhances the</p> <p>8 ability to make inferences from the results of a</p> <p>9 meta-analysis.</p> <p>10 In observational epidemiology, this</p> <p>11 isn't true. We have very different kinds of study</p> <p>12 design and problems that arise in different</p> <p>13 studies, and this leads in itself to variability</p> <p>14 and heterogeneity. And it is sometimes imagined</p> <p>15 that heterogeneity is a reflection -- some sort of</p> <p>16 a reflection of different risks in different</p> <p>17 populations or something like that. It's mainly</p> <p>18 -- it's at least in part a reflection of the fact</p> <p>19 that different study designs and different -- just</p> <p>20 not just the overall architecture of the design,</p> <p>21 but the implementation, how people were</p> <p>22 interviewed, what the questions were and so on,</p> <p>23 influences the results of a study. That varies</p> <p>24 from study to study, and that creates</p> <p>25 heterogeneity. So --</p>
<p style="text-align: right;">Page 179</p> <p>1 you teach a class on epidemiological</p> <p>2 methodologies; is that correct?</p> <p>3 A Yes.</p> <p>4 Q Okay. So presumably, when you teach a</p> <p>5 class you discuss the strengths and the</p> <p>6 limitations of different types of analyses. Fair?</p> <p>7 A It comes into the course, yes.</p> <p>8 Q Okay. So in the context of looking at</p> <p>9 the strengths and the weaknesses of different</p> <p>10 types of analyses, are there any weaknesses or</p> <p>11 limitations to a meta-analysis?</p> <p>12 A Weakness, okay. Because the word</p> <p>13 "limitation" doesn't always mean weaknesses.</p> <p>14 Meta-analysis depends on having reliable</p> <p>15 data. So the basic studies that you use and the</p> <p>16 basic data that you use in a meta-analysis has to</p> <p>17 be sufficiently reliable to support a good</p> <p>18 meta-analysis.</p> <p>19 The data have to be sufficiently</p> <p>20 comparable in nature. So putting apples and</p> <p>21 oranges and grapes into the same meta-analysis</p> <p>22 would be a problem. Different kinds of apples,</p> <p>23 yes, but different -- et cetera. So you have to</p> <p>24 be careful that you're really measuring the same</p> <p>25 thing, have the same outcomes.</p>	<p style="text-align: right;">Page 181</p> <p>1 Q Does heterogeneity -- do you want</p> <p>2 heterogeneity in a meta-analysis? Is it a good</p> <p>3 thing or does it weaken the meta-analysis?</p> <p>4 A It depends on the purpose of the</p> <p>5 meta-analysis. So some meta-analyses have as one</p> <p>6 of their objectives to identify populations in</p> <p>7 which the effect of the drug or the -- whatever</p> <p>8 you're studying is different from one population</p> <p>9 to another. That is a situation where you want to</p> <p>10 identify heterogeneity, and you want to try to</p> <p>11 target heterogeneity and the different</p> <p>12 populations, different studies, the different</p> <p>13 methods of administering medication, or whatever</p> <p>14 the differences are between studies.</p> <p>15 In observational epidemiology, it's</p> <p>16 rarely the case that heterogeneity -- that a</p> <p>17 formal evaluation of heterogeneity is -- is useful</p> <p>18 or actionable. Usually the bottom line result</p> <p>19 doesn't change. For example, there are</p> <p>20 meta-analyses of smoking and lung cancer where the</p> <p>21 meta-analysis demonstrates heterogeneity of the</p> <p>22 results. The results are always between a</p> <p>23 relative risk of 5 or 6 and a relative risk of 10</p> <p>24 or 12.</p> <p>25 Now, for the question of -- for the</p>

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<p style="text-align: right;">Page 182</p> <p>1 qualitative question does smoking cause lung 2 cancer, it really doesn't matter if the relative 3 risk is 5 or 12. So that heterogeneity has 4 absolutely no bearing on the question that is 5 being asked, and the best answer ignore -- would 6 ignore heterogeneity. It doesn't really matter. 7 If you're trying to find out in which 8 populations does smoking have a greater impact, 9 then you might want to say, Okay, let's -- which 10 are the populations where the relative risks were 11 5 and which are populations where the relative 12 risks are 12? Can we identify differences between 13 it? Are they different countries, different 14 ethnic groups, and so on and so forth. 15 So it's a longwinded answer, and I'm not 16 sure if that gets to the question that you were 17 asking. 18 Q Well, you said in your report -- and 19 it's on page 17, if you want to look at it -- you 20 stated -- it's at the top of the page. 21 A Yes. 22 Q "Unless a significant methodological 23 flaw can be identified that has caused the 24 heterogeneity, the best overall estimate remains 25 the meta-estimate."</p> <p style="text-align: right;">Page 183</p> <p>1 Did I read that correctly? 2 A Yeah. I guess we should read the 3 beginning of the sentence just to -- oh, yes. Oh, 4 yes, I see. Sorry. Yes, I agree with you. 5 Q So what is the basis for that statement? 6 A The basis is that it's correct. Are you 7 offering an alternative to this that I should 8 consider? 9 Q Is there -- I guess my question is, is 10 it -- is it correct because you think it is 11 correct? Or can you point me to something that 12 would support that principle and explain it more 13 fully? 14 A I -- I haven't looked for any 15 documentary evidence that this has been written up 16 in this way anywhere. I've been interpreting 17 meta-analyses in this way, and I believe this to 18 be true. 19 Q Okay. So we talked about a few 20 different things that you articulated as potential 21 weaknesses to a meta-analysis. Are there any 22 other weaknesses to a meta-analysis? 23 A Possibly. Are there any that you can 24 identify? I will be happy to -- you know, I'm 25 just -- to meta-analysis as a concept, I think one</p>	<p style="text-align: right;">Page 184</p> <p>1 of the weaknesses is that it is sometimes 2 fetishized, and that people put too much -- you 3 know, have sort of a magical belief in the value 4 of meta-analysis result, which is not justified. 5 Often the results of certain critical studies are 6 as valuable or more valuable than those of a 7 meta-analysis, especially when -- especially in 8 observational epidemiology when it's hard to 9 really identify all of the parameters that 10 influence the quality of a study. 11 And so determining what studies to 12 include and which data from each study to include 13 is tricky. It requires judgment. Those judgments 14 can be wrong. They can be contested. Sometimes 15 one very good study is as powerful, but -- it's 16 part of -- a meta-analysis is part of a package of 17 information that I would look at in evaluating the 18 risks. 19 Q Okay. You mentioned the concept that a 20 scientific judgment needs to be used in 21 determining what studies and, more specifically, 22 what data within those studies to include in a 23 meta-analysis, correct? 24 A That's correct. 25 Q And you would agree that -- and I</p> <p style="text-align: right;">Page 185</p> <p>1 believe you just referenced it -- that there can 2 be errors in judgment in determining what studies 3 to include or not include or what data to include 4 or not include, correct? 5 A I -- 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: I would not characterize 8 these things as errors in judgment. There can be 9 differences in judgment that are legitimate 10 that -- where people, equally well motivated and 11 well trained and experienced, can arrive at 12 different judgments on some of these things. 13 BY MS. BRANSCOME: 14 Q Did you have a specific methodology that 15 you used in determining which relative risk or 16 odds ratio to include from each of the studies 17 that you include in your meta-analysis? 18 A Carefully reading the study, carefully 19 reading the tables and the reports of what is in 20 the paper, understanding what is there, and then 21 making a determination on that basis. 22 Q And those were, to use your words, 23 quote, judgment calls; is that fair? 24 A Yes. 25 Q Okay.</p>
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<p>1 A There is no alternative to judgment in 2 science. 3 Q The meta-analysis in your MDL report is 4 different than the meta-analysis in your 2016 5 report; is that correct? 6 A The bottom line result, you're saying? 7 Well, yes, but also in the 2016 report, I 8 presented I think eight different estimates, 9 depending on scenarios of which studies to include 10 and which result from which studies to include, 11 because there were some borderline judgments where 12 I thought the best thing would be just -- just 13 provide all of the different options. 14 In 2018, I adopted a different strategy. 15 I thought, well, the best service I can provide 16 the court is to give my best estimate of which 17 studies and which data to include, and then to 18 provide a set of alternatives that I call 19 sensitivity analyses. So that's one difference 20 between the two reports. 21 Q Okay. 22 A But there were some differences in which 23 studies were included and which result in which 24 studies were included from the one to the other. 25 Q Well, let me start at the very basic</p>	<p>1 is the difference doing it this way or doing it 2 that way. 3 Q Okay. 4 A But it's largely overlapped. I mean, 5 I'll look at it and see if I can quickly recognize 6 which studies might have been -- 7 Q Well, I can point you -- 8 A Okay. If you've done it, that's great. 9 Q Yeah. So you included Green 1997 in 10 your 2016 meta-analysis, correct? 11 A Yes. 12 Q And you did not include Green 1997 in 13 your 2018 meta-analysis, correct? 14 A Correct. 15 Q Why did you -- did including Green 1997 16 in your earlier report, do you consider that to be 17 a flaw? 18 MS. PARFITT: Objection to form. 19 THE WITNESS: I don't consider any of 20 these things flaws. They were judgment calls, and 21 I -- actually, in that case, I learned in between 22 some information that I didn't know in 2016 that 23 made that decision the right one. 24 BY MS. BRANSCOME: 25 Q What information did you learn?</p>
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<p>1 level. Are there any studies that are included in 2 your 2018 meta-analysis that were not available at 3 the time that you did your 2016 meta-analysis? 4 A I don't think so. 5 Q Okay. So you mention that you made some 6 changes to which studies you included and even 7 within that, some of your numbers are slightly 8 different. 9 Can you explain to me what changes you 10 made with respect to which studies to include? 11 A So somewhere I did the side-by-side 12 comparison, and I don't think I have -- I don't 13 think I have that with me. So it would take me a 14 bit of time to just compare the two and see how -- 15 how they compare. 16 Q So you generated actually a side-by-side 17 comparison of your 2016 meta-analysis and your 18 2018 meta-analysis? 19 A Well, of -- of the studies that went 20 into them. Well, generated is a kind of a 21 highfalutin word. I listed on a piece of paper, 22 and then I -- beside it I listed the other ones. 23 So I'm pretty sure I did that at some point just 24 to make sure. If I didn't do it on paper, I did 25 it in my mind. I wanted to know, you know, what</p>	<p>1 A Well, a case-control study was carried 2 out in Australia by a team that involved Green and 3 Purdie, and the publication in 1995, I think it 4 was, described their analysis -- sorry, do you 5 want me to stop while you're -- 6 Q Keep going. 7 A The paper in Purdie 1995, I think it is, 8 described the association between talc and ovarian 9 cancer. I had that in my database. 10 And I also had -- a couple of years 11 later, there was a paper by Green that was not 12 focused on talc. It was focused on risks that 13 were related to -- to other -- well, to other 14 gynecological issues in relation to ovarian 15 cancer. But in there she -- in the text, not in 16 any table but in the text, she provided a result 17 on talc and ovarian cancer. 18 Because that paper was published in 19 2000 -- in 1997, the Green, et al., paper, I 20 assumed that that was an extension of the 2000 -- 21 of the data that was used for the 1995 paper, and 22 that it actually included more information and 23 more up-to-date information than the 1995 paper 24 published two years earlier. I had some doubts 25 about that. But that was the decision I made in</p>

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<p>1 2016. In general, when there were different 2 reports from the same study at different 3 intervals, I took the most recent one as being the 4 more definitive one.</p> <p>5 When I started analyzing for the 2018 6 report, I had lingering -- I remained with the 7 lingering doubts about the Green study -- the 8 Green report and whether it actually was an 9 updated version of the talc results from 2016 -- 10 from my 2016 report.</p> <p>11 And I wrote to Adele Green, who I know 12 as an acquaintance, not well but enough to write 13 and say, You know, what's going on with these -- 14 what was going on with these two papers? Is it 15 the fact that the result -- which one has the most 16 definitive result on talc and ovarian cancer, the 17 earlier one or the more recent one? And she wrote 18 back and said, The earlier one does. That the 19 later one -- and I can't remember the exact 20 explanation, but it had to do with some cases 21 being dropped because of reasons having nothing to 22 do with talc but having to do with other 23 hypotheses that she was examining.</p> <p>24 So in any case, the two results are 25 identical. So it makes no difference. But that</p>	<p>1 studies over time, the relative risk for the 2 association between peritoneal use of -- I mean 3 perineal use of talc and the development of 4 ovarian cancer has actually gone down?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: I -- I haven't evaluated 7 that, and I have no reason to agree or disagree 8 with it. If you want me to spend a bit of time 9 looking to see if I can --</p> <p>10 BY MS. BRANSCOME:</p> <p>11 Q Well, for example --</p> <p>12 A -- confirm or --</p> <p>13 Q You are familiar with the Berge 2018 14 paper, correct?</p> <p>15 A Yeah, yeah.</p> <p>16 Q And the authors in that paper said: "We 17 confirm the trend toward lower overall risk 18 estimates as more evidence accumulated."</p> <p>19 MS. PARFITT: Can we get that article in 20 front of him?</p> <p>21 MS. BRANSCOME: Of course.</p> <p>22 MS. PARFITT: Thank you.</p> <p>23 MS. BRANSCOME: It is tab 48. (A discussion was held off the record.)</p> <p>24 MS. PARFITT: It's tab 18?</p>
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<p>1 is, in answer to your question, why did it change, 2 it wasn't capricious issues. It wasn't wrong. It 3 was the right thing to do.</p> <p>4 Q Did you retain copies of the e-mail 5 correspondence that you had with Green?</p> <p>6 A I imagine that I did, but I -- this 7 would have been eight months ago maybe or 8 something.</p> <p>9 Q Would it be fair to say that you relied 10 on Green's representation of which dataset was 11 more fulsome in determining what to use in your 12 2018 metadata?</p> <p>13 A Yes.</p> <p>14 Q And that was something she communicated 15 to you by e-mail, correct?</p> <p>16 A That's right.</p> <p>17 MS. BRANSCOME: We can meet and confer 18 about this offline, but we would request 19 production of those e-mails.</p> <p>20 MS. PARFITT: We'll take it under 21 advisement. Thank you.</p> <p>22 MS. BRANSCOME: Okay.</p> <p>23 BY MS. BRANSCOME:</p> <p>24 Q Do you agree that in terms of the trend 25 for relative risk, with the addition of newer</p>	<p>1 THE WITNESS: Tab 48?</p> <p>2 BY MS. BRANSCOME:</p> <p>3 Q Tab 48.</p> <p>4 A I don't have a tab 48.</p> <p>5 Q It may be in your second binder.</p> <p>6 A Oh.</p> <p>7 MS. PARFITT: I will take this one out. 8 And I'll take this one for you.</p> <p>9 THE WITNESS: Thank you.</p> <p>10 MS. PARFITT: Of course.</p> <p>11 THE WITNESS: Thank you.</p> <p>12 BY MS. BRANSCOME:</p> <p>13 Q Dr. Siemiatycki, are you familiar with 14 the article that is located there behind tab 48?</p> <p>15 A Yes, I am.</p> <p>16 Q Berge is the lead author on this 17 publication titled "Genital use of talc and risk 18 of ovarian cancer: A meta-analysis." Correct?</p> <p>19 A Yes, correct.</p> <p>20 Q I believe earlier you said that Berge 21 "beat you to the punch" might have been the phrase 22 that you used.</p> <p>23 What did you mean by that?</p> <p>24 A If this had never appeared, I might have 25 worked on a manuscript to submit for publication</p>

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<p>1 on my meta-analysis before today, sometime in the 2 past. 3 Q Do you rely on Berge 2018? 4 MS. BRANSCOME: Let's go ahead and mark 5 that actually as Exhibit 12. 6 (Exhibit No. 12 was marked for 7 identification.) 8 MR. TISI: How long have we been going? 9 How long have we been going? 10 MS. BRANSCOME: Just under five hours. 11 MR. TISI: No, how long have we been 12 going on this one? 13 MS. BRANSCOME: We can take a break 14 if -- do you need a break? 15 MR. TISI: I'm just asking. 16 MS. PARFITT: Do you want a break? 17 THE WITNESS: No, let's finish -- let's 18 finish with this. 19 MS. PARFITT: Okay. 20 (A discussion was held off the record.) 21 BY MS. BRANSCOME: 22 Q Do you rely in forming your opinions on 23 this case on the Berge article that we just marked 24 as Exhibit 12? 25 A I formed my opinions before knowing</p>	<p>1 here that I'm -- I haven't fully integrated into 2 my evaluation of this paper. But I know what's in 3 it. I know what's the other one. I know what's 4 in this one. 5 Q Okay. So back to my question, 6 Dr. Siemiatycki. 7 A Yeah. 8 Q You stated that you believe that the 9 Berge 2018 study supports the conclusions that you 10 have reached in this litigation, and my question 11 to you was, what do you mean by that? 12 A Well, it supports it in a few ways. 13 One -- and from my point of view, the most 14 important one, but probably not for anyone else -- 15 is that they carried out a search of the 16 literature using a much more intensive and -- a 17 much more intensive procedure than I had. I had 18 full confidence in the procedure that I had used, 19 but it was not as long, as lengthy, as costly, et 20 cetera, et cetera, as what -- and the bottom line 21 was that they didn't find any papers -- relevant 22 papers that I hadn't found. So I was very 23 reassured by this. 24 The second thing is that the bottom line 25 meta-analysis result -- well, no, the second thing</p>
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<p>1 about this article. 2 Q Do you believe that the Berge 2018 study 3 supports the conclusions that you have reached in 4 your own meta-analysis? 5 A Yes, I think it does. 6 Q In what way? 7 A Well, let me preface that also by saying 8 that there's been a bit of a -- a history to this 9 article of -- I thought the publication -- there 10 was a version published in 2017, which I thought 11 was the definitive version that I've always kept 12 in my binders as the Berge article, and it's only 13 very recently that I actually came upon this 14 particular version, which is not greatly changed 15 from the 2017 but slightly changed, and I haven't 16 fully digested the small changes that have been 17 made. 18 Q If you could -- sorry for the multiple 19 binders, but if you want to look at your first 20 binder, tab 13, we can see if that's the paper 21 that you previously had reviewed as the Berge 22 paper. 23 A I -- I don't mind answering questions in 24 relation to this version. Just -- I just wanted 25 to point out that there are a couple of things</p>	<p>1 is that the actual results that they chose from 2 the different studies were very similar in most 3 cases to the ones I had chosen from the different 4 study. So there was a degree of corroboration 5 there that I was happy about. 6 They adopted a different strategy in one 7 important respect, and that concerned how to deal 8 with the Terry paper and the various components of 9 the Terry paper. And with all due respect to this 10 team, I don't think that there -- theirs was in 11 error. I prefer my approach that maintained the 12 integrity of the pooled analysis, which has some 13 advantages. But there's -- you know, I wouldn't 14 expect any large differences on the bottom line 15 estimates from their strategy or my strategy. And 16 the bottom line results were very similar. 17 They -- also in the previous version, 18 their evaluation of dose-response was, in my view, 19 deficient in not devoting adequate weight to what 20 I think is the most important evidence around 21 dose-response in this area, which is the Terry 22 pooled analysis. They focused on studies which 23 provided results by duration of exposure and by 24 frequency of exposure. And I think it's the 25 combination of those two which is the most</p>

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<p>1 important metric.</p> <p>2 And the fact that the Terry analysis was</p> <p>3 able to combine an enormous dataset for evaluating</p> <p>4 dose-response, much greater than any of the</p> <p>5 studies looking at duration or any of the studies</p> <p>6 looking at frequency, meant that in my view they</p> <p>7 missed an opportunity to properly evaluate</p> <p>8 dose-response by cumulative exposure.</p> <p>9 I note very recently that they have --</p> <p>10 they've now used a different statistical procedure</p> <p>11 for evaluating dose-response by duration and</p> <p>12 frequency, which is embodied in their Table 3,</p> <p>13 which I don't fully understand. It seemed -- this</p> <p>14 was the new part of this study, which I haven't --</p> <p>15 I looked quickly in the method section to see a</p> <p>16 description of exactly what they did, and I</p> <p>17 couldn't find it, but I don't deny that it's</p> <p>18 somewhere in the article. I just haven't had time</p> <p>19 to properly evaluate that part of it.</p> <p>20 Q As you sit here today, do you have any</p> <p>21 criticisms of the statistical analysis that they</p> <p>22 performed?</p> <p>23 A All of it? You're referring to all of</p> <p>24 it? Well, I --</p> <p>25 MS. PARFITT: Objection. Form.</p>	<p>1 That's 2016. Okay.</p> <p>2 Q Dr. Siemiatycki, if you could just</p> <p>3 identify for the record where you're looking so I</p> <p>4 can follow along and the record reflects it.</p> <p>5 A Right. I'm looking in my report of 2018</p> <p>6 in the appendix, page 103, Appendix B.</p> <p>7 Q So looking at Appendix B, which also</p> <p>8 helpfully compares Penninkilampi as well, are</p> <p>9 there studies specifically focused on the Berge</p> <p>10 2018 that in your opinion the authors should have</p> <p>11 included in their meta-analysis?</p> <p>12 MS. PARFITT: Objection. Form.</p> <p>13 THE WITNESS: Okay. Well, just</p> <p>14 following this table, I see that Gates 2008 was in</p> <p>15 my report, but not in theirs. Now, it wasn't in</p> <p>16 my main analysis; it was in one of my sensitivity</p> <p>17 analyses. So I have no -- my main analysis and</p> <p>18 their main analysis concurred about Gates.</p> <p>19 The next one that I see that was in my</p> <p>20 analysis but not in theirs was what I call</p> <p>21 Schildkraut B. And Schildkraut B, for the record,</p> <p>22 is -- there's no such study, but I've named it</p> <p>23 Schildkraut B. It's the result of the analysis of</p> <p>24 the Schildkraut study of cases that were</p> <p>25 interviewed before 2014, I think it was.</p>
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<p>1 THE WITNESS: I note that their bottom</p> <p>2 line meta-relative risk is lower than the one that</p> <p>3 I estimated. And I'm not sure why that is. To me</p> <p>4 the -- the difference in -- the minor differences</p> <p>5 in the studies included or excluded is not</p> <p>6 sufficient to explain that, and I wonder if it's a</p> <p>7 software issue, of them having used a different</p> <p>8 software for meta-analysis than I used. But it's</p> <p>9 not a criticism necessarily. I just note this</p> <p>10 discrepancy.</p> <p>11 BY MS. BRANSCOME:</p> <p>12 Q Are there any studies that you included</p> <p>13 in your meta-analysis in 2018 that the Berge</p> <p>14 authors failed to consider that you think they</p> <p>15 should have included?</p> <p>16 A So I'll go back to my report, because I</p> <p>17 do have a table outlining that in my report.</p> <p>18 MS. PARFITT: You want your report?</p> <p>19 THE WITNESS: Yeah, my report, back to</p> <p>20 my report.</p> <p>21 MS. PARFITT: Let me get you that.</p> <p>22 BY MS. BRANSCOME:</p> <p>23 Q And we'll take a break after we finish</p> <p>24 this paper.</p> <p>25 A Thank you.</p>	<p>1 BY MS. BRANSCOME:</p> <p>2 Q And we will discuss that in more detail,</p> <p>3 but do you consider it an error for the Berge</p> <p>4 authors to just have taken the Schildkraut 2016</p> <p>5 data as a whole?</p> <p>6 A No, I don't consider it an error. In</p> <p>7 fact, I used it -- not in my main analysis but in</p> <p>8 one of my sensitivity analyses.</p> <p>9 The same with Shushan. So Shushan '96</p> <p>10 was in my -- one of my sensitivity analyses, not</p> <p>11 in my main analysis, and they did not include it</p> <p>12 in their main analysis. So we agreed on the main</p> <p>13 analyses there.</p> <p>14 Terry, I included in mine, and they</p> <p>15 didn't include Terry. They included the component</p> <p>16 parts of Terry.</p> <p>17 So there was no -- there was no study</p> <p>18 that was in my main analysis that was not in</p> <p>19 theirs.</p> <p>20 Q Okay. And looking quickly back at the</p> <p>21 Berge article, coming full circle to the question</p> <p>22 that I started with, if you could look on page 253</p> <p>23 of that paper.</p> <p>24 MS. PARFITT: Yes, 253.</p> <p>25 BY MS. BRANSCOME:</p>

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<p>1 Q Under the Discussion section, do you see 2 where I am? 3 A Yes, I do. 4 Q All right. The second paragraph under 5 Discussion from the Berge paper states: "This 6 meta-analysis suggests that genital powder use is 7 associated with a small increased risk of 8 developing ovarian cancer. However, this positive 9 association appears to be limited to the serous 10 histological type and to case-control studies." 11 Did I read that correctly? 12 A You read it correctly. 13 Q It continues on: "This estimate is 14 somewhat lower than that of previous 15 meta-analysis," and in parentheses, it refers 16 specifically to Huncharek and Langseth, colon, "In 17 our cumulative meta-analysis, we confirmed the 18 trend toward lower overall risk estimates as more 19 evidence accumulated." 20 First, did I read that correctly? 21 A You read it correctly. 22 Q Do you have any basis to disagree with 23 the statement by the Berge authors in this 24 paragraph in the Discussion section? 25 MS. PARFITT: Objection. Form.</p>	<p>1 BY MS. BRANSCOME: 2 Q Based on the evidence that's available 3 today, do you think there is strong enough 4 epidemiological evidence to reach a conclusion 5 about the association between talc -- genital talc 6 use and other specific subtypes of ovarian cancer? 7 A I think it becomes very fragile to draw 8 inferences about other types. And in the absence 9 of reliable evidence about other types, you know, 10 especially those that have a smaller fraction of 11 all ovarian cancers than serous type, I think the 12 prudent thing to do is to consider that all 13 ovarian cancers are affected the same way. 14 The same way as with -- we do with lung 15 cancer and smoking and histologic types of lung 16 cancer. While there is some variability in the 17 degree of relative risk between smoking and 18 adenocarcinoma or squamous cell carcinoma or other 19 types, small cell, large cell, for lung cancer, 20 there is some variability in the degree of 21 relative risk. Generally speaking, we say smoking 22 causes cancer. Smoking causes all kinds of -- 23 causes lung cancer, all kinds of lung cancer. 24 Q Are you qualified to evaluate the 25 reasonableness of making an extrapolation from one</p>
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<p>1 THE WITNESS: So there are a few 2 statements in this paragraph, not just one. 3 Do you want me to take them one by one? 4 BY MS. BRANSCOME: 5 Q Sure. 6 A So whether "the positive association 7 appears to be limited to the serous histological 8 type," I have some problem with that. I -- I was 9 looking in their publication for which studies -- 10 let me just see if I can -- which studies provided 11 evidence on serous type, and I couldn't find that. 12 In my -- in my analysis, the evidence 13 that I was able to -- to compile that's in this 14 addendum and meta-analyze showed an approximately 15 similar meta-relative risk between serous and all 16 ovarian cancers. 17 So there is no -- I found no evidence 18 that this -- that there was a particular peak of 19 risk for serous types compared to other types. 20 Q As you sit here today -- 21 MS. PARFITT: Are you done -- are you 22 done with your -- is that -- 23 THE WITNESS: Yeah, for -- for that 24 point on serous, yes. 25 MS. PARFITT: Thank you.</p>	<p>1 subtype of ovarian cancer to all types of ovarian 2 cancer in terms of what is biologically plausible? 3 MS. PARFITT: Objection to form. 4 THE WITNESS: My inferences would be 5 based on the statistical and epidemiological 6 evidence, and if there is biological, 7 physiological evidence that would indicate that 8 talcum powder is more likely to influence one type 9 of ovarian cancer than another, I would be 10 absolutely open to that interpretation. 11 BY MS. BRANSCOME: 12 Q All right. So moving along in that 13 paragraph, are there -- 14 A Okay. 15 Q -- any other sentences or portions of 16 sentences with which you disagree? 17 A So, the statement about case-control 18 studies and whether the positive association is 19 limited to case-control studies is -- is a bit 20 contentious. And I understand very well that the 21 evidence does not -- if we only had the cohort 22 studies, if that's all the evidence that existed, 23 it would be fair to say that that evidence does 24 not argue for an association with -- between 25 ovarian cancer and -- so I would -- I'm not -- I</p>

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<p>1 guess if I were writing this, I would qualify it</p> <p>2 somehow, and -- no, I think I'll just leave --</p> <p>3 leave that there, and you may have follow-up</p> <p>4 questions about the case-control/cohort</p> <p>5 comparison.</p> <p>6 Q Is there anything else in this paragraph</p> <p>7 in the Discussion section of Berge 2018 with which</p> <p>8 you disagree?</p> <p>9 MS. PARFITT: And can you refer him to</p> <p>10 the left-hand side of the discussion or the</p> <p>11 entire --</p> <p>12 MS. BRANSCOME: The second full</p> <p>13 paragraph in the Discussion section.</p> <p>14 MS. PARFITT: Which starts with "An</p> <p>15 important."</p> <p>16 THE WITNESS: So I -- I think what --</p> <p>17 BY MS. BRANSCOME:</p> <p>18 Q No, it begins with "This meta-analysis</p> <p>19 suggests."</p> <p>20 A Yeah. Yeah.</p> <p>21 So your question -- the question is</p> <p>22 about that sentence that says: "This estimate is</p> <p>23 somewhat lower. In our cumulative meta-analysis,</p> <p>24 we confirmed the trend towards lower," da, da, da,</p> <p>25 and that refers I guess specifically to Figure 4</p>	<p>1 misstates his testimony.</p> <p>2 THE WITNESS: It requires looking at</p> <p>3 which studies were included in each of these</p> <p>4 meta-analyses, and which results were chosen by</p> <p>5 the meta-analysis people who did these</p> <p>6 meta-analyses from each paper. The meta-analysis</p> <p>7 is somewhat sensitive to which studies are</p> <p>8 selected and -- so the same study might have been</p> <p>9 selected in the 2004 meta-analysis as in the 2016,</p> <p>10 but they chose -- they decided to choose an</p> <p>11 estimate from -- a result from that paper that</p> <p>12 they thought was the most reasonable one and</p> <p>13 that's different.</p> <p>14 So one would have to do side-by-side</p> <p>15 comparisons of which studies were included and</p> <p>16 which results before concluding that this is</p> <p>17 because of a downward trend. You also need to</p> <p>18 know when the data were collected.</p> <p>19 You know, I'm not sure if the -- if you</p> <p>20 are implying or if they are implying that -- you</p> <p>21 know, I -- a declining trend, if there is one, in</p> <p>22 meta-analyses -- these are the years of the</p> <p>23 meta-analysis, not the years that women were</p> <p>24 exposed. So there's no implication -- direct</p> <p>25 implication here that the risks to women are</p>
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<p>1 on the following page.</p> <p>2 Certainly the confidence intervals, if</p> <p>3 you look at the confidence intervals of the</p> <p>4 meta-estimates in that Figure 4, from 1988 through</p> <p>5 2016, everything is embedded in everything. So</p> <p>6 from the point of view of statistical variability,</p> <p>7 it would be difficult to argue that there is a</p> <p>8 real statistical -- statistically meaningful</p> <p>9 difference between the trendline from -- through</p> <p>10 that whole period.</p> <p>11 There is a tendency by eye for a</p> <p>12 decline. I don't know in their paper, in the text</p> <p>13 whether they've characterized the decline with any</p> <p>14 regression coefficients or not. I don't remember.</p> <p>15 It seems to me like a rather weak trend to make a</p> <p>16 big point about. So I wouldn't disagree with</p> <p>17 the -- the point they're making, but I think it's</p> <p>18 not strongly supported. There isn't a strong</p> <p>19 trend downwards in this line, in this figure.</p> <p>20 Q So you would agree with the authors that</p> <p>21 there is a downward trend in the risk assessment</p> <p>22 over time as more evidence accumulated, but you</p> <p>23 might disagree with them about the strength of</p> <p>24 that trend. Is that fair?</p> <p>25 MS. PARFITT: Objection. Form,</p>	<p>1 declining over time. So if it's only the fact</p> <p>2 that meta-analyses carried out at different points</p> <p>3 in time showed very slightly different results, I</p> <p>4 don't find that a noteworthy observation. But...</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q And you agree that meta-analyses are</p> <p>7 sensitive to the judgments applied by the authors</p> <p>8 of those studies, correct?</p> <p>9 A Yes, they are, but to -- to a degree. I</p> <p>10 mean you have to weigh the -- the degree of</p> <p>11 bias -- or not the bias, but the -- the influence</p> <p>12 of particular decisions that you might make.</p> <p>13 I've done an analysis looking at what</p> <p>14 happens when you include or exclude studies, and</p> <p>15 you could exclude any study from my meta-analysis</p> <p>16 and you'd find the same result. So if any of</p> <p>17 these studies in my meta-analysis are completely</p> <p>18 wrong, if they were completely invented, if the</p> <p>19 women were never actually interviewed but the</p> <p>20 investigator just wrote a paper on a Sunday</p> <p>21 afternoon, and you're suspicious that this study</p> <p>22 was -- or badly -- whatever, if you take any one</p> <p>23 of these studies and take it out of the mix, it</p> <p>24 wouldn't affect the meta-relative risk.</p> <p>25 MS. BRANSCOME: Okay. I think this is a</p>

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<p>1 good place to take a break.</p> <p>2 MS. PARFITT: Very good. Thank you.</p> <p>3 THE VIDEOGRAPHER: We're going off the</p> <p>4 record at 5:07 p.m.</p> <p>5 (Recess.)</p> <p>6 THE VIDEOGRAPHER: This begins disc</p> <p>7 number 5 in the deposition of Jack Siemiatycki.</p> <p>8 We're going back on the record at 5:36 p.m.</p> <p>9 BY MS. BRANSCOME:</p> <p>10 Q One of the decisions that you had to</p> <p>11 make in conducting your meta-analysis was how to</p> <p>12 treat the Schildkraut 2006 study, correct?</p> <p>13 A 2000 --</p> <p>14 Q -- '16.</p> <p>15 A Thank you. Yes.</p> <p>16 Q Okay. For purposes of your</p> <p>17 meta-analysis, you divided Schildkraut 2016 into</p> <p>18 two sets of results, correct?</p> <p>19 A "Divided" isn't quite the right word.</p> <p>20 Q How would you describe it?</p> <p>21 A Because they're not separate, one</p> <p>22 includes the other.</p> <p>23 Q Okay.</p> <p>24 A So just the word "divided" -- I'm not</p> <p>25 sure what the right word is, but there were two</p>	<p>1 Q But if it's your preference to look at</p> <p>2 the paper now, it is tab 15.</p> <p>3 A It's in this binder, I think.</p> <p>4 MS. PARFITT: Here it is. Thank you.</p> <p>5 THE WITNESS: Thank you.</p> <p>6 Okay. The -- so one includes all --</p> <p>7 Schildkraut A includes all of the cases</p> <p>8 interviewed the whole period, and the</p> <p>9 Schildkraut B includes cases after 2014, but I'm</p> <p>10 not sure if it includes 2014. But...</p> <p>11 BY MS. BRANSCOME:</p> <p>12 Q Let me ask a clarification on that one,</p> <p>13 Dr. Siemiatycki.</p> <p>14 Schildkraut 2016-B shows results for</p> <p>15 individuals interviewed before 2014, correct?</p> <p>16 A I'm sorry, which one, B? Schildkraut B?</p> <p>17 Q Schildkraut 2016-B.</p> <p>18 A B.</p> <p>19 Q I believe you just stated after, so I --</p> <p>20 A I see. Okay.</p> <p>21 Q -- wanted to seek clarification there.</p> <p>22 A Okay. Yeah, I'm --</p> <p>23 Q If it's helpful --</p> <p>24 A It's late in the day. Let me --</p> <p>25 Q Sure. If it's helpful to you to</p>
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<p>1 sets of results reported, and I used both sets of</p> <p>2 results. One is embedded -- one set is embedded</p> <p>3 in the other.</p> <p>4 Q So correct me if I'm wrong, Schildkraut</p> <p>5 2016-A shows results from all subjects who were</p> <p>6 interviewed in the study from 2010 through 2015.</p> <p>7 Schildkraut 2016-B is a subset of that that</p> <p>8 includes the results for subjects who were</p> <p>9 interviewed before 2014, correct?</p> <p>10 MS. PARFITT: And, Counsel, if we could</p> <p>11 get Schildkraut in front of him, would that be all</p> <p>12 right?</p> <p>13 MS. BRANSCOME: Sure.</p> <p>14 BY MS. BRANSCOME:</p> <p>15 Q If you need to reference it --</p> <p>16 MS. PARFITT: Sure.</p> <p>17 BY MS. BRANSCOME:</p> <p>18 Q -- to answer my questions, certainly.</p> <p>19 A If you're going -- yes, I think you're</p> <p>20 right in what you said, but if you want me to look</p> <p>21 at specific results in the paper, maybe I should</p> <p>22 have it in front of me.</p> <p>23 Q I was going to direct you there when we</p> <p>24 got to those questions.</p> <p>25 A Okay.</p>	<p>1 reference in your report, you discuss your</p> <p>2 separation of Schildkraut on page 74, Note 6.</p> <p>3 A That's why I wanted my report in a small</p> <p>4 binder, rather than -- before 2014, yes.</p> <p>5 Q And the reason that you divided --</p> <p>6 separated the study into those two groups, one</p> <p>7 which is inclusive of the other, is to account for</p> <p>8 the possibility that publicity surrounding two</p> <p>9 class action lawsuits on talc and ovarian cancer</p> <p>10 in 2014 may have induced bias in the validity of</p> <p>11 reporting talc exposure; is that correct?</p> <p>12 A That's correct.</p> <p>13 Q Okay. But in your main meta-analysis</p> <p>14 you use Schildkraut A, which includes all subjects</p> <p>15 interviewed from 2010 to 2015, correct?</p> <p>16 A That's correct.</p> <p>17 Q When you substituted Schildkraut B,</p> <p>18 which included only subjects interviewed before</p> <p>19 2014, for Schildkraut A, all subjects interviewed</p> <p>20 from 2010 to 2015, the relative risk estimate for</p> <p>21 the meta-analysis goes down, correct?</p> <p>22 A Yes. From 1.28 to 1.27.</p> <p>23 MS. BRANSCOME: If we could mark</p> <p>24 Schildkraut as Exhibit 13.</p> <p>25 THE WITNESS: There's a label here</p>

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<p>1 already.</p> <p>2 MS. PARFITT: There is. I will go ahead</p> <p>3 and just -- you don't care -- there's a defense</p> <p>4 label of 1436. Can I go ahead and put the exhibit</p> <p>5 over top of it? Does it matter to you? Okay.</p> <p>6 This will be 13.</p> <p>7 (Exhibit No. 13 was marked for</p> <p>8 identification.)</p> <p>9 BY MS. BRANSCOME:</p> <p>10 Q All right. If you could,</p> <p>11 Dr. Siemiatycki, please turn to Table 2, which is</p> <p>12 on page 1414 of Exhibit 13.</p> <p>13 A I see it.</p> <p>14 Q Before doing that, can you just simply</p> <p>15 confirm that Exhibit 13 is in fact the Schildkraut</p> <p>16 study?</p> <p>17 A Yes, it is.</p> <p>18 Q And we see in Table 2 that there is a</p> <p>19 category for interview date less than 2014, and</p> <p>20 then another category for interview date greater</p> <p>21 than 2014. Correct?</p> <p>22 A Yes, I see that.</p> <p>23 Q All right. And we see that there are</p> <p>24 odds ratios for any genital use for both of these</p> <p>25 categories, correct?</p>	<p>1 A Yes, that's correct.</p> <p>2 Q All right. And the -- those are for the</p> <p>3 cases, meaning individuals who had been diagnosed</p> <p>4 or reported as diagnosed with ovarian cancer,</p> <p>5 correct?</p> <p>6 A Correct.</p> <p>7 Q And if you compare that against the</p> <p>8 controls, 34 percent is the reported number for</p> <p>9 women without ovarian cancer who reported any</p> <p>10 genital use of talcum powder that were interviewed</p> <p>11 before 2014, correct?</p> <p>12 A That's correct.</p> <p>13 Q And if we look at those same</p> <p>14 percentages for the individuals who were</p> <p>15 interviewed after 2014, the percentage of cases,</p> <p>16 meaning individuals who have been diagnosed or</p> <p>17 reported as diagnosed with ovarian cancer who</p> <p>18 claim to have used talc genitally at any point in</p> <p>19 time, goes up to 51.5 percent compared to a</p> <p>20 control of 34.4 percent, correct?</p> <p>21 A That's correct.</p> <p>22 Q All right. And so if we compare</p> <p>23 individuals interviewed before 2014 who have been</p> <p>24 diagnosed or reported as diagnosed with ovarian</p> <p>25 cancer to those individuals in the same category</p>
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<p>1 A Yes, I see that.</p> <p>2 Q And the odds ratio for any genital use</p> <p>3 for individuals who were interviewed after 2014 is</p> <p>4 higher than the odds ratio for any genital use for</p> <p>5 those individuals who were interviewed before</p> <p>6 2014, correct?</p> <p>7 A That's correct.</p> <p>8 Q And it also shows the number of</p> <p>9 individuals that fell in those respective</p> <p>10 categories, correct?</p> <p>11 A Yes, correct.</p> <p>12 Q And so just simply looking at the</p> <p>13 reported data, the percentage of women with --</p> <p>14 with ovarian cancer who reported any genital use</p> <p>15 of talc who were interviewed before 2014 was</p> <p>16 36.5 percent, correct?</p> <p>17 A Can you run that by me again? Show me</p> <p>18 where the --</p> <p>19 Q Sure.</p> <p>20 A So interview date before 2014, any</p> <p>21 genital use, the percentage 36.5, number 128, is</p> <p>22 that what --</p> <p>23 Q Yes.</p> <p>24 A -- you are looking at? Okay.</p> <p>25 Q Was that correct?</p>	<p>1 who were interviewed after 2014, you see at least</p> <p>2 a 12 percent increase in those figures; is that</p> <p>3 correct?</p> <p>4 A 12 percent representing which -- which</p> <p>5 two numbers?</p> <p>6 Q Representing the difference between the</p> <p>7 cases who reported genital use of talcum powder --</p> <p>8 A The 36.5?</p> <p>9 Q -- as compared to the 51.5 percent.</p> <p>10 A So you -- you said it's 12 percent? I</p> <p>11 think it's like 14 percent.</p> <p>12 Q It is.</p> <p>13 A Okay.</p> <p>14 Q That is correct.</p> <p>15 But if you do the same comparison for</p> <p>16 the control group, you don't see a similar</p> <p>17 increase or a similar difference in the reporting</p> <p>18 percentages for individuals interviewed before</p> <p>19 2014 as after 2014, correct?</p> <p>20 A That's correct.</p> <p>21 Q Okay. Are those results compatible with</p> <p>22 the existence of recall bias for individuals</p> <p>23 interviewed after 2014?</p> <p>24 A I would say they are compatible with</p> <p>25 recall bias.</p>

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<p>1 Q Okay. Was litigation-related recall 2 bias considered by IARC as a possible bias that 3 could explain the association between perineal 4 talc use and ovarian cancer? 5 A In 2006? 6 Q Correct. 7 A I -- I can't remember verbatim the 8 discussions, and I can't remember a discussion of 9 litigation-related impact on response bias. I 10 doubt if there would have been any at that time, 11 but -- and I don't recall any discussion of it. 12 Q And at least the Schildkraut authors are 13 identifying 2014 as a significant year with 14 respect to widespread knowledge of lawsuits 15 involving talcum powder and a claim of ovarian 16 cancer -- 17 MS. PARFITT: Objection. Form. 18 BY MS. BRANSCOME: 19 Q -- correct? 20 MS. PARFITT: Objection. Form. 21 THE WITNESS: I -- if you may, I think 22 what they refer to is localized publicity, not 23 widespread publicity. 24 BY MS. BRANSCOME: 25 Q If you can, can you refer me to the</p>	<p>1 column seems to suggest that data was collected 2 from a number -- 3 A Oh. 4 Q -- of different states across the United 5 States, correct? 6 A Correct. Correct. 7 Q And so at least based on your review as 8 you sit here today, the authors do not seem to 9 have limited the potential effect of publicity of 10 the class action lawsuits to a precise region, 11 correct? 12 A That seems to be the case. 13 Q Okay. 14 A Yes. 15 Q And so your understanding or your 16 testimony earlier that the publicity was only 17 localized, you're not able to point me to anything 18 in the article to support that, correct? 19 A That's correct. 20 Q And in fact, in the two portions of the 21 Schildkraut article that discuss the publicity, 22 there is no specific reference to it being limited 23 to an area, correct? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: In the two -- sorry.</p>
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<p>1 language in the paper that references that. 2 A So I see a mention of it in the -- on 3 page 1412, second column, last paragraph, about 4 seven or eight lines from the bottom, the sentence 5 beginning: "Two class action lawsuits were filed 6 in 2014 concerning possible carcinogenic effects 7 of body powder, which may have influenced recall." 8 Now, there's a reference there, but the 9 reference doesn't indicate where those class 10 actions were. And now I'm going to look in the 11 Discussion section to see if there's any 12 indication. If anyone knows whether there is or 13 if there is not -- I haven't looked for this 14 specifically. I just have a vague memory of them 15 referring to localized publicity, but... (peruses 16 document.) 17 Well, in my very quick scanning, I don't 18 see reference to these being local. You people 19 might know whether these two lawsuits that they 20 refer to in the Reference section, whether they 21 were local in this area. And this is North 22 Carolina, is it? 23 Q Well, so that's -- that's a question I 24 have for you, Dr. Siemiatycki. On page 1412, the 25 paragraph -- the last full paragraph on the second</p>	<p>1 BY MS. BRANSCOME: 2 Q So there's one discussion of the 3 potential public -- the potential effect of 4 publicity, which is on page 1412. 5 A Yeah. 6 Q And then there is a second discussion of 7 it on page 1416 -- 8 A Yes. 9 Q -- in the Discussion section, and 10 neither of those two sections talk about awareness 11 of the class action lawsuits being limited to a 12 specific geographic region, correct? 13 A That's correct. 14 Q In fact, the language that the authors 15 use is a heightened awareness of the exposure as a 16 result of two recent class action lawsuits, and 17 they discuss just publicity, correct? 18 A Yes, I think so. 19 Q Okay. Are you relying -- 20 A In that second paragraph in the 21 discussion, the authors seem to discount the -- 22 the recall bias hypothesis or to minimize it, and 23 I -- I -- I don't support -- or the opposite of 24 what they're saying. I just note that they don't 25 seem to be enthusiastic about that hypothesis that</p>

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<p>1 it's strictly due to response bias.</p> <p>2 But go ahead and --</p> <p>3 Q The authors do recognize, though, that</p> <p>4 there is a possibility of recall bias may have</p> <p>5 caused some inflation of the odds ratios, correct?</p> <p>6 A Yes.</p> <p>7 MS. PARFITT: Wait, that's part --</p> <p>8 that's part of the sentence. Objection.</p> <p>9 THE WITNESS: Yeah. Yeah.</p> <p>10 BY MS. BRANSCOME:</p> <p>11 Q Are you relying on Penninkilampi 2018</p> <p>12 for your opinions in this litigation?</p> <p>13 A My opinions were informed before I knew</p> <p>14 about that article.</p> <p>15 Q Do you believe that the Penninkilampi</p> <p>16 2018 study supports your conclusions in this</p> <p>17 litigation?</p> <p>18 A It's consistent with my conclusions. A</p> <p>19 little bit like Berge, the fact that they didn't</p> <p>20 pick up any studies that I hadn't -- that I had</p> <p>21 not picked up reassures me that there was nothing</p> <p>22 amiss in my search of the literature.</p> <p>23 There were some differences in which</p> <p>24 studies they included in their meta-analysis and</p> <p>25 which data. I'm happy with the decisions -- the</p>	<p>1 impact on the bottom line result. Some errors</p> <p>2 might have large effects, so it would depend what</p> <p>3 the errors were.</p> <p>4 But since his studies were mostly the</p> <p>5 same as the ones I had used and the same ones that</p> <p>6 Berge had used, and since the results that he had</p> <p>7 taken out of those studies were mostly the same</p> <p>8 ones I had taken out and that Berge had taken out,</p> <p>9 I fully expected his bottom line meta-analysis to</p> <p>10 produce the same results.</p> <p>11 BY MS. BRANSCOME:</p> <p>12 Q The Penninkilampi study does not</p> <p>13 consider or include the Gates 2010 cohort study,</p> <p>14 correct?</p> <p>15 A Correct.</p> <p>16 Q Do you think Gates 2010 - and if you</p> <p>17 would prefer to refer to Penninkilampi, it is</p> <p>18 tab 20.</p> <p>19 A Yeah.</p> <p>20 Q In your opinion, is --</p> <p>21 MS. PARFITT: I have a clean one right</p> <p>22 here with the -- if we use two books, we can do it</p> <p>23 to save time, but --</p> <p>24 THE WITNESS: Sorry?</p> <p>25 MS. PARFITT: Do you want that?</p>
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<p>1 judgments I had made about it. So there are some</p> <p>2 minor variations there. But essentially they</p> <p>3 found the same thing that I found, because we're</p> <p>4 all working with the same data.</p> <p>5 Q Okay. Did you do an independent</p> <p>6 verification that the data Penninkilampi reports</p> <p>7 in his article is indeed accurate?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: By the data, you mean the</p> <p>10 results that he put into his meta-analysis?</p> <p>11 BY MS. BRANSCOME:</p> <p>12 Q For example, did you look at the</p> <p>13 reported data in the tables in the Penninkilampi</p> <p>14 article and compare it to the underlying studies</p> <p>15 to see if they matched?</p> <p>16 A I don't recall doing that comparison.</p> <p>17 I'm not sure why I would want to.</p> <p>18 Q If there were errors in the reporting of</p> <p>19 any of the odds ratios or confidence intervals in</p> <p>20 the Penninkilampi 2018 paper, would that call into</p> <p>21 reliability the meta-analysis, in your opinion?</p> <p>22 MS. PARFITT: Objection. Form.</p> <p>23 THE WITNESS: It depends on the nature</p> <p>24 of the errors. If there was one decimal point</p> <p>25 typo sort of thing, it would have absolutely no</p>	<p>1 THE WITNESS: No. I'm actually looking</p> <p>2 for my copy of the Gates 2010.</p> <p>3 You're going to ask me about his use</p> <p>4 of -- Gates 2010?</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q I was simply just going to ask you, is</p> <p>7 Gates 2010 a significant study, in your opinion,</p> <p>8 to leave out of a meta-analysis on this topic?</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 THE WITNESS: A significant study.</p> <p>11 It -- in my view there are flaws with that study,</p> <p>12 but there are flaws with many epidemiologic</p> <p>13 studies. It's not -- that's not a reason to</p> <p>14 exclude them. I would include it but take note of</p> <p>15 the flaws, including the fact that their reference</p> <p>16 category for their odds ratios for their relative</p> <p>17 risk estimates was not an unexposed group, but it</p> <p>18 was a group that combined women who had never used</p> <p>19 talc with women who had used it occasionally.</p> <p>20 BY MS. BRANSCOME:</p> <p>21 Q Are there any other errors in the Gates</p> <p>22 2010 study? And if you'd like to refer to it --</p> <p>23 MS. PARFITT: Thank you.</p> <p>24 THE WITNESS: Okay. Let me find my copy</p> <p>25 of -- yeah, here we are -- Gates 2010.</p>

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<p>1 Well, yes, there are some flaws with it, 2 but they're related to the fact that this builds 3 on the Nurses' Health Study, which is a good and 4 well deservedly recognized, good prospective 5 cohort study which focused on many factors in 6 women's lives, including predominantly nutritional 7 reproductive, hormonal factors, and all kinds of 8 diseases, all heart disease, diabetes, et cetera, 9 et cetera. There have been hundreds and hundreds 10 of publications that have come out of it. 11 Their collect- -- the collection of talc 12 information in the Nurses' Health Study was very 13 weak. The questionnaire was conducted in 1982. 14 It was part of a biannual follow-up mailed 15 questionnaire. The question itself and the 16 structure of the question itself I find very weak 17 from the point of view of designing questions for 18 questionnaires. I mean, I -- I could read it into 19 the record, but it's in the -- it's in the -- it's 20 quoted in the Gertig paper, and it's actually -- 21 I've seen that page of the questionnaire, and 22 it's -- I find it ambiguous as to how women would 23 answer that question. 24 And it's only one question for that 25 point in time. There was never any follow-up. So</p>	<p>1 authors of the Penninkilampi 2018 publication? 2 A No, I don't. 3 Q Do you know or have any information 4 about the source or sources of funding for the 5 Penninkilampi article? 6 A No, I don't, no. I -- I would add, 7 though, that the inclusion or exclusion of Gates 8 2010 probably didn't affect the bottom line result 9 of their meta-analysis by more than 0.01 decimal 10 point of the odds ratio. 11 Q But did they publish any type of 12 sensitivity analysis that would let you 13 specifically draw that conclusion? 14 A Well, I -- I have done one myself where 15 I dropped each of the studies in order to see what 16 would be the impact if that study had been 17 dropped. And there's hardly -- no study has more 18 than a 1 decimal -- you know, 0.01 decimal point 19 on the odds ratio. 20 So we could argue about the merits of 21 any of these studies or demerits, but the impact 22 of including them or excluding an individual study 23 is pretty minimal. 24 Q Shushan 1996 is one of the studies you 25 did not include in your main meta-analysis,</p>
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<p>1 between 1982 and 2007 or so, when the follow-up of 2 the -- for the Gates analysis ended, they had no 3 idea whether women were exposed -- whether women 4 who had been exposed in 1982 were in exactly the 5 same exposure category in 1990, in 2000, in 2005 6 and so on. They made the assumption that women's 7 exposure status was stable for 25 years. And so 8 that's a major weakness of the analysis of talc 9 and ovarian cancer in -- from this study. 10 BY MS. BRANSCOME: 11 Q So in your view, was it proper for the 12 Penninkilampi authors to leave Gates 2010 out of 13 their meta-analysis? 14 A That's not what I said. That's not what 15 I said. 16 I -- I think to go down the road of 17 making value judgments about each of these studies 18 and including them or not including them would end 19 up in the need for many days of deposition and 20 cross-examination, because each of those -- any 21 decision about any study can be argued umpteen 22 ways. And that's why I took the decision early on 23 not to make exclusions based on my judgment of the 24 quality of the study. 25 Q Do you personally know any of the</p>	<p>1 correct? 2 A Correct. 3 Q And you reported that you did not 4 include it because the report was quite cryptic 5 regarding the data collection and the talc 6 exposure variable, correct? 7 A That's correct. 8 Q What did you mean by the report was 9 quite cryptic regarding the data collection? 10 A So I have to take a couple of minutes to 11 review that -- to look at that paper to answer 12 your question. 13 Well, so the first thing that strikes 14 me -- and I haven't read the description of how 15 they collected the data. The first thing that 16 strikes me is they have a table, Table 2 on 17 page 15, with some information about these various 18 variables, including talc exposure. And the two 19 categories of talc exposure that they describe in 20 this table, one is called "Never - seldom," and 21 the other one is called "Moderate - a lot." I 22 don't know what that means. So that's one 23 element -- how they present it and how they 24 analyze the data. 25 But I think actually how they collected</p>

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<p>1 the data also led me to describe the -- the 2 information on exposure as being cryptic. 3 Q Okay. Are you familiar with the 2018 4 paper by Mohamed Taher and others entitled "The 5 systematic review and meta-analysis: The 6 association between perineal use of talc and risk 7 of ovarian cancer"? 8 A Yes, I am. 9 Q Okay. Have you read the Taher 2018 10 manuscript? 11 A Yes. I haven't read all the appendices, 12 but I basically read enough that I know what's in 13 it. 14 Q Did you have access to the Taher 2018 15 article before it was published? 16 A I don't think it's been published. 17 Q How did you get access to the Taher 18 manuscript and the appendices? 19 A I heard about -- I first heard about the 20 Canadian Department of Health advisory, or 21 whatever the word is, about talc and ovarian 22 cancer in the public media. And I -- I think in 23 the news report that I saw, there was a reference 24 to Taher -- the Taher paper. That's how I first 25 learned about something by them.</p>	<p>1 Q Which author do you know? 2 A Daniel Krewski. 3 Q You have published many papers with, is 4 it, Dr. Krewski? 5 A Yes. 6 Q Is that correct? 7 A Yes. Yes, it is. 8 Q How many papers have you published with 9 him? 10 A I'll look at my CV and count. 11 Q Would it be fair to say over 20? 12 A Oh, I would be surprised if it was that 13 high. But if you've counted, I won't contradict 14 what you -- what you say. 15 Q Let's do it this way: Would all of the 16 papers that you have coauthored with Dr. Krewski 17 be listed on your CV? 18 A Yes. 19 Q Have you discussed your opinion on talc 20 and ovary -- ovarian cancer with Dr. Krewski? 21 A No. 22 Q Have you discussed your opinion on talc 23 and ovarian cancer with any of the authors of the 24 Taher manuscript? 25 A No.</p>
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<p>1 And I wrote to Ms. Parfitt -- I sent a 2 message to Ms. Parfitt asking her if she knows 3 anything about this and has that information, and 4 she wrote back, I think, and said, No, I thought 5 you might have -- know something about it and have 6 information. 7 MS. PARFITT: And -- and, 8 Dr. Siemiatycki, you're not to discuss -- 9 THE WITNESS: Okay. 10 MS. PARFITT: -- discuss our 11 communications. 12 THE WITNESS: Okay. 13 Subsequently, Ms. Parfitt sent me the 14 Taher paper. 15 BY MS. BRANSCOME: 16 Q And when -- when did you first request 17 the Taher paper and appendices from Ms. Parfitt? 18 A I think in December 2018. 19 Q When were you provided with the Taher 20 manuscript and the appendices and supplemental 21 tables? 22 A Within a few days after that. 23 Q Do you know personally any of the 24 authors on the Taher manuscript? 25 A I know one of them.</p>	<p>1 Q Have you spoken to or otherwise 2 communicated with Dr. Krewski about your 3 involvement as an expert in this litigation? 4 A No, I haven't. 5 Q Do you know if the Taher manuscript has 6 been accepted for publication? 7 A I don't know if it's been submitted for 8 publication. 9 Q Do you know anything about the source or 10 sources of funding for the Taher 2018 manuscript? 11 A I don't have any privileged information 12 about that, but I seem to recall in the manuscript 13 they're saying something about funding from Health 14 Canada. 15 Q Is it fair to say that your knowledge 16 with respect to the source or sources of funding 17 of the Taher manuscript is limited to what is 18 written in the manuscript itself? 19 A Yes. 20 Q Did you attend the National Cancer 21 Institute directors meeting held in Lyon, France, 22 on July 11th through 13th, 2018? 23 A No, I did not. 24 Q Now, the Taher 2018 manuscript contains 25 a meta-analysis, correct?</p>

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<p>1 A Correct.</p> <p>2 Q And Taher 2018 calculates an overall</p> <p>3 relative risk of 1.28, correct?</p> <p>4 MS. PARFITT: If we could just get that</p> <p>5 in front of him.</p> <p>6 MS. BRANSCOME: Oh, of course.</p> <p>7 MS. PARFITT: Do you have your copy? I</p> <p>8 appreciate that.</p> <p>9 MS. BRANSCOME: It is tab --</p> <p>10 MS. PARFITT: I think he may have it as</p> <p>11 well and --</p> <p>12 THE WITNESS: I have it --</p> <p>13 MS. PARFITT: Make that a little easier</p> <p>14 and more quicker.</p> <p>15 MR. TISI: Do you want to mark it?</p> <p>16 MS. BRANSCOME: We have already marked</p> <p>17 Dr. Siemiatycki's binder.</p> <p>18 MR. TISI: Okay. We can --</p> <p>19 MS. BRANSCOME: I believe that contains</p> <p>20 the -- the manuscript and the exhibits.</p> <p>21 MS. PARFITT: And that is binder 6,</p> <p>22 Exhibit 6.</p> <p>23 MR. TISI: You said binder, going with</p> <p>24 his or the one --</p> <p>25 MS. PARFITT: Exhibit 6.</p>	<p>1 one in the binders you gave him? That may help.</p> <p>2 MS. BRANSCOME: It's tab 31.</p> <p>3 MS. PARFITT: Thank you.</p> <p>4 Tab 31. I appreciate that.</p> <p>5 No, you can keep yours.</p> <p>6 THE WITNESS: Okay.</p> <p>7 MS. PARFITT: There you go, just for the</p> <p>8 record. Okay. Thank you.</p> <p>9 BY MS. BRANSCOME:</p> <p>10 Q So my question to you, Dr. Siemiatycki,</p> <p>11 is Taher 2018 calculates an overall relative risk</p> <p>12 of 1.28. Is that correct?</p> <p>13 A That's what it says in the abstract,</p> <p>14 yes.</p> <p>15 Q And the confidence interval that they</p> <p>16 report is 1.2 to 1.37, correct?</p> <p>17 A Yes.</p> <p>18 Q So the overall relative risk as well as</p> <p>19 the confidence interval reported in the Taher 2018</p> <p>20 paper is very similar to the overall relative risk</p> <p>21 and confidence interval that you report in your</p> <p>22 analysis for the MDL, correct?</p> <p>23 A That's correct. Which is not</p> <p>24 surprising.</p> <p>25 Q And if you could turn to page 49 of the</p>
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<p>1 MS. BRANSCOME: Exhibit 6 is</p> <p>2 Dr. Siemiatycki's copy of the Taher manuscript</p> <p>3 with the appendices and supplemental tables.</p> <p>4 BY MS. BRANSCOME:</p> <p>5 Q Is that correct?</p> <p>6 A That's correct.</p> <p>7 MR. TISI: And that's in his binder,</p> <p>8 Exhibit 6.</p> <p>9 THE WITNESS: I don't -- I didn't bring</p> <p>10 the supplemental tables and appendices with me.</p> <p>11 BY MS. BRANSCOME:</p> <p>12 Q Okay. So could you just describe for</p> <p>13 the record the contents of Exhibit 6. It is</p> <p>14 marked, but just so that I can follow along.</p> <p>15 A This document?</p> <p>16 MR. TISI: No, the whole thing.</p> <p>17 THE WITNESS: Oh, the whole -- the whole</p> <p>18 thing. It contains various meta-analyses, so the</p> <p>19 Berge, Penninkilampi, Huncharek, just the meta --</p> <p>20 main meta-analyses that have been done.</p> <p>21 MS. PARFITT: And, Counsel --</p> <p>22 THE WITNESS: Langseth.</p> <p>23 MS. PARFITT: Right.</p> <p>24 -- in light of the fact he has his in</p> <p>25 front of him, Exhibit 6, is there a corresponding</p>	<p>1 Taher paper. You see the Conclusion section?</p> <p>2 A Yes.</p> <p>3 Q The authors of the Taher paper state in</p> <p>4 the Conclusion section: "Consistent with previous</p> <p>5 evaluations, the IARC in 2010 and subsequent</p> <p>6 evaluations by individual investigators, the</p> <p>7 present comprehensive evaluation of all currently</p> <p>8 available relevant data indicates that perineal</p> <p>9 exposure to talc powder is a possible cause of</p> <p>10 ovarian cancer in humans."</p> <p>11 First, did I read that correctly?</p> <p>12 A Yes.</p> <p>13 Q Okay. Do you agree first that the Taher</p> <p>14 2018 paper represents a comprehensive evaluation</p> <p>15 of all currently available relevant data?</p> <p>16 A Yes. I haven't -- I haven't done the</p> <p>17 same comparison between which studies and which</p> <p>18 data points from each study they used compared to</p> <p>19 the ones that I've used. I did that for the Berge</p> <p>20 and for the Penninkilampi, comparing theirs with</p> <p>21 mine. I haven't done that for theirs. So I -- I</p> <p>22 assume that they used basically the same studies</p> <p>23 and the same results from each study.</p> <p>24 But, you know, to answer -- I'm quite</p> <p>25 sure that they did this comprehensive evaluation</p>

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<p>1 of all currently available, but to answer that</p> <p>2 strictly, I would want to do a comparison of the</p> <p>3 two. But I'm willing to accept.</p> <p>4 Q Okay. And we see here even in this</p> <p>5 sentence that we just read that there's a</p> <p>6 reference there to the IARC publication in 2010.</p> <p>7 We've already discussed that, correct?</p> <p>8 A Yes.</p> <p>9 Q And then there's a reference to</p> <p>10 subsequent evaluations by individual</p> <p>11 investigators, and there's a reference there to</p> <p>12 articles or studies 3, 5 and 69. Do you see that?</p> <p>13 A I see that.</p> <p>14 Q And looking at the reference pages,</p> <p>15 beginning on page 51, would you agree that</p> <p>16 reference 3 is the Berge analysis, this citation</p> <p>17 is to 2017, correct?</p> <p>18 A Correct.</p> <p>19 Q Five is Penninkilampi, correct?</p> <p>20 A Correct.</p> <p>21 Q And the last reference, which is 69, is</p> <p>22 to the Terry meta-analysis. Do you see that?</p> <p>23 A Terry is not a meta-analysis. It's a</p> <p>24 pooled analysis. But I see that, yes.</p> <p>25 Q Okay. So the reference in the Taher</p>	<p>1 Q And that they examined those studies</p> <p>2 closely enough at least to reach the conclusion in</p> <p>3 their own mind that their results were consistent</p> <p>4 with those findings.</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MS. BRANSCOME:</p> <p>8 Q Are there any scientific publications</p> <p>9 that were available to you during your review in</p> <p>10 connection with your formation of opinions in the</p> <p>11 MDL that were not available to the authors of the</p> <p>12 Taher manuscript?</p> <p>13 MS. PARFITT: Objection. Form.</p> <p>14 THE WITNESS: So are you talking about</p> <p>15 the meta-analysis that -- are you talking about</p> <p>16 studies that went into meta-analysis or are you</p> <p>17 talking about the, you know, 200 or 300 references</p> <p>18 in my bibliography?</p> <p>19 BY MS. BRANSCOME:</p> <p>20 Q Fair enough.</p> <p>21 Are there any studies that you included</p> <p>22 in your meta-analysis that, at least to your</p> <p>23 knowledge, were available to you and were not</p> <p>24 available to the Taher authors?</p> <p>25 MS. PARFITT: Objection. Form.</p>
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<p>1 manuscript to reference 69 is to the Terry pooled</p> <p>2 analysis from 2013, correct?</p> <p>3 A Correct.</p> <p>4 Q And so you agree that at least the Taher</p> <p>5 authors considered the Berge, Penninkilampi, and</p> <p>6 Terry studies.</p> <p>7 MS. PARFITT: Objection. Form.</p> <p>8 THE WITNESS: Were aware of. I'm not</p> <p>9 sure what you mean by considered. They -- they</p> <p>10 referenced it. I don't know that they considered</p> <p>11 it in their -- I don't imagine that there's any</p> <p>12 place in their statistical analysis where they</p> <p>13 introduced data from any of those papers. They're</p> <p>14 just acknowledging that those other meta-analyses</p> <p>15 found the same thing that they found.</p> <p>16 BY MS. BRANSCOME:</p> <p>17 Q So perhaps we have a different</p> <p>18 understanding of the word "considered."</p> <p>19 A Okay.</p> <p>20 Q Would you agree that a fair reading of</p> <p>21 their Conclusion paragraph would indicate that the</p> <p>22 Taher authors were first aware --</p> <p>23 A Yes.</p> <p>24 Q -- of Terry, Berge and Penninkilampi?</p> <p>25 A Yes.</p>	<p>1 THE WITNESS: Oh, they would have been</p> <p>2 available because all of my -- the studies I used</p> <p>3 are in publicly available literature, and I'm sure</p> <p>4 they were available.</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q Okay. Do you have any criticisms of the</p> <p>7 Taher 2018 meta-analysis?</p> <p>8 A I haven't evaluated it closely enough</p> <p>9 to -- to formulate criticisms or praise or --</p> <p>10 Q Now, you testified earlier that there</p> <p>11 was a flurry of activity in December surrounding</p> <p>12 the information from Health Canada and the Taher</p> <p>13 manuscript.</p> <p>14 Is there a reason why you have not</p> <p>15 reviewed the Taher manuscript in detail and formed</p> <p>16 an opinion about whether you agree or disagree</p> <p>17 with its analysis?</p> <p>18 MS. PARFITT: Objection. Fully</p> <p>19 misstates his testimony. Form.</p> <p>20 THE WITNESS: I -- I thought that it</p> <p>21 would have absolutely no bearing on the results</p> <p>22 and the opinions that I expressed in my report,</p> <p>23 plus I didn't have time to do such a review. And</p> <p>24 so the combination of those two things made it a</p> <p>25 simple decision not to devote precious time and</p>

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<p style="text-align: right;">Page 242</p> <p>1 effort to a -- a futile activity. 2 I'm not uninterested in what they did or 3 what they found, but I can predict pretty quickly 4 what they did and what they found, and I -- I know 5 the studies that they reviewed, that they had 6 access to. There's nothing that they would find 7 that I wouldn't be able to predict. 8 MS. BRANSCOME: Okay. 9 Now may be a good time to take a break. 10 MS. PARFITT: Sure. Okay. Very good. 11 MS. BRANSCOME: Let's go off the record. 12 MR. TISI: Are we switching examiners 13 too? 14 MS. BRANSCOME: I don't know. That's 15 why -- 16 MS. PARFITT: Oh, fair enough. Fair 17 enough. 18 THE VIDEOGRAPHER: We're going off the 19 record at 6:22 p.m. 20 (Recess.) 21 THE VIDEOGRAPHER: This begins disc 22 number 5 in the deposition of Jack Siemiatycki. 23 We are going back on the record at 6:40 p.m. 24 BY MS. BRANSCOME: 25 Q So, Dr. Siemiatycki, if you could open</p>	<p style="text-align: right;">Page 244</p> <p>1 criteria, but which are not criteria and shouldn't 2 be called criteria. 3 Q Understanding that you have specific 4 views about the appropriateness and application of 5 it, you are at least familiar with what is 6 sometimes referred to as a Bradford Hill analysis 7 or the Hill criteria, correct? 8 A I don't -- again, the phrase "Bradford 9 Hill analysis" doesn't mean anything. I don't 10 think you would find that phrase in any 11 epidemiology or statistics textbook. 12 Q Are you saying as you sit here today, 13 Dr. Siemiatycki, you've never heard of the Hill 14 criteria? 15 MS. PARFITT: Objection. Misstates his 16 testimony. 17 THE WITNESS: No, I've heard of it, and 18 I'm saying that it's a misnomer. And so I'd 19 prefer if the correct terminology is used when -- 20 if you're asking me questions about it. 21 BY MS. BRANSCOME: 22 Q The authors of the Taher manuscript use 23 the term "Hill criteria" -- 24 A Yes. 25 Q -- in their Table 2, correct?</p>
<p style="text-align: right;">Page 243</p> <p>1 back up to the Taher manuscript again. I believe 2 it's in your binder that's been marked as 3 Exhibit 6, and specifically, if you could go to 4 Figure 3 on page 39. 5 Have you looked at Figure 3 from the 6 Taher 2018 manuscript before now? 7 A No, I haven't. I may have glanced at it 8 going through it, but I haven't examined it. 9 Q Did you look at anything in the Taher 10 manuscript to support your opinion that there is 11 at least evidence compatible with the dose- 12 response relationship between perineal use of talc 13 and ovarian cancer? 14 A I didn't look for that in this paper. 15 Q If you could look at page 25 of the 16 Taher paper. 17 Do you see here that the authors of the 18 Taher manuscript describe the summary of evidence 19 for each of the Hill criteria of causation? Do 20 you see that? 21 A I see that. 22 Q And you are familiar with the Hill -- 23 the Hill criteria of causation, correct? 24 A I'm familiar with what they call the 25 Hill criteria and what some people call the Hill</p>	<p style="text-align: right;">Page 245</p> <p>1 A Yes, they do. 2 Q And there is a discussion under the -- 3 what they refer to as a criterion for strength of 4 association, correct? 5 A Yes. 6 Q And the Taher authors report that out of 7 30 epidemi- -- epidil- -- epidemiological studies -- 8 it's late in the day -- six reported positive 9 association of statistical significance with a 10 risk value, relative risk or odds ratio of 1.5 or 11 greater. 12 Is that description of the 13 epidemiological studies accurate? 14 A I don't know. I haven't counted. I 15 haven't done that kind of counting, which is 16 irrelevant and wrong from a statistical and 17 epidemiological point of view to do it. So I 18 haven't done it, and I can't confirm that there 19 are six that report odds ratios greater than 1.5. 20 I could do that if you want me to. I can look 21 through studies and see. 22 But there's no -- there's no scientific 23 purpose in doing that. It's a meaningless piece 24 of information. 25 Q Would you criticize the Taher authors</p>

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<p>1 for their discussion of the Hill criteria?</p> <p>2 A Yes.</p> <p>3 Q And you have explained your criticisms</p> <p>4 about the Hill criteria in both your trial</p> <p>5 testimony and in your prior deposition testimony,</p> <p>6 correct?</p> <p>7 A I can't remember the details, but I -- I</p> <p>8 guess if I was asked about it, I explained what I</p> <p>9 thought about it.</p> <p>10 My criticism -- I'm not sure what you</p> <p>11 mean by my criticisms of the term or of the</p> <p>12 concepts that the paper that Hill wrote in 1965,</p> <p>13 the ways -- the umpteen different ways that other</p> <p>14 people have interpreted it. What -- what are you</p> <p>15 referring to when you say I criticized? What did</p> <p>16 I criticize?</p> <p>17 Q Have your views with respect to the use</p> <p>18 and application of the so-called Hill criterion</p> <p>19 changed since you testified in the Echeverria</p> <p>20 trial?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 THE WITNESS: They -- they haven't</p> <p>23 changed in 40 years.</p> <p>24 BY MS. BRANSCOME:</p> <p>25 Q Okay. Thank you.</p>	<p>1 Q 48 in my binder, but I don't know if you</p> <p>2 have a copy in yours, which might be faster.</p> <p>3 A No, this -- I have the -- I have the</p> <p>4 current Berge paper. So...</p> <p>5 Q At page 9, I believe.</p> <p>6 Well, that's confusing to say page 9.</p> <p>7 A Okay, I see that.</p> <p>8 Q Okay. In reviewing the conclusion that</p> <p>9 the Berge authors reached, would -- did the Berge</p> <p>10 authors conclude that genital talc use was a</p> <p>11 probable cause of ovarian cancer?</p> <p>12 A They did not indicate that they</p> <p>13 concluded that.</p> <p>14 Q Okay. And same for the Penninkilampi</p> <p>15 study.</p> <p>16 MS. PARFITT: Had you finished? Had you</p> <p>17 finished your statement.</p> <p>18 THE WITNESS: Not quite.</p> <p>19 There's a difference between the</p> <p>20 findings of a study and the inferences that are</p> <p>21 drawn from those findings. So the findings of</p> <p>22 their meta-analyses and the findings of the</p> <p>23 Penninkilampi meta-analyses and findings of the</p> <p>24 Taher meta-analyses are the same as my findings.</p> <p>25 All four agree on the findings.</p>
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<p>1 Now, we have just discussed three</p> <p>2 meta-analyses: The Berge meta-analyses, the</p> <p>3 Penninkilampi meta-analyses, and the Taher</p> <p>4 meta-analyses. Correct?</p> <p>5 A Yes.</p> <p>6 Q Would you agree that none of the authors</p> <p>7 of those three meta-analyses concluded that talc</p> <p>8 was a probable cause of ovarian cancer?</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 THE WITNESS: The purpose of those</p> <p>11 meta-analyses was to estimate the meta-estimate of</p> <p>12 relative risk. In terms of the conclusion about</p> <p>13 probable causation, I think they all commented on</p> <p>14 it in their discussions.</p> <p>15 And can you specify your question again,</p> <p>16 whether they concluded that it was a probable</p> <p>17 cause?</p> <p>18 BY MS. BRANSCOME:</p> <p>19 Q Correct.</p> <p>20 A I'd have to look at the way they -- what</p> <p>21 conclusions they drew, I'd have to look at that.</p> <p>22 Q Okay. If we could look at the Berge</p> <p>23 paper, which should be tab --</p> <p>24 A Let me see, I think I have the latest</p> <p>25 issue of the Berge paper.</p>	<p>1 Interpreting and making inferences is a</p> <p>2 whole other bailiwick, a whole other activity, and</p> <p>3 they don't -- didn't conclude in this section that</p> <p>4 it's a probable cause. From the same evidence, I</p> <p>5 do conclude that it's a probable cause.</p> <p>6 BY MS. BRANSCOME:</p> <p>7 Q Right. And the same is true for the</p> <p>8 Penninkilampi officer -- authors, correct?</p> <p>9 A Sorry, I have to go through it.</p> <p>10 (Peruses document.)</p> <p>11 I don't really agree with your</p> <p>12 statement. I don't think they conclude that it's</p> <p>13 probable or not probable. I don't see -- can you</p> <p>14 point me to a statement that would imply that it's</p> <p>15 not -- that they think it's not probable?</p> <p>16 Q Do the authors of the Penninkilampi</p> <p>17 paper use the phrase, quote, suggestive of a</p> <p>18 causal association, in the Conclusion section?</p> <p>19 A Yes, they do.</p> <p>20 Q Okay. Would you say that "suggestive of</p> <p>21 a causal association" is equivalent to probable</p> <p>22 causation?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 THE WITNESS: That's a semantic</p> <p>25 question, and how different people and different</p>

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<p>1 cultures -- and I think these people are</p> <p>2 Australians -- how Australians tend to use the</p> <p>3 word "suggestive." I -- I don't read this in a</p> <p>4 way as to suggest that they don't think it's</p> <p>5 probable.</p> <p>6 BY MS. BRANSCOME:</p> <p>7 Q So you don't know from reviewing the</p> <p>8 Conclusion section one way or the other whether</p> <p>9 the Penninkilampi authors view perineal use of</p> <p>10 talc as a probable cause of ovarian cancer.</p> <p>11 MS. PARFITT: Objection. Form,</p> <p>12 misstates his testimony.</p> <p>13 Just answer the question.</p> <p>14 THE WITNESS: Yes, that's right, I -- I</p> <p>15 don't.</p> <p>16 BY MS. BRANSCOME:</p> <p>17 Q Okay. And as we just looked at in the</p> <p>18 Taher manuscript, the Taher authors describe that</p> <p>19 the data indicates perineal exposure to talc</p> <p>20 powder is a possible cause of ovarian cancer in</p> <p>21 humans, correct?</p> <p>22 And if you need the reference, it's</p> <p>23 page 49.</p> <p>24 A That's correct.</p> <p>25 Possible does not preclude probable, by</p>	<p>1 "possible" here can cover a range of possibilities</p> <p>2 that includes probable.</p> <p>3 So if something is possible, that means</p> <p>4 it could happen, and in their view or in some of</p> <p>5 their -- those authors' view, the possibility or</p> <p>6 the probability of -- of such a thing happening</p> <p>7 might be greater than 50 percent, and they might</p> <p>8 still describe it as a possible cause of ovarian</p> <p>9 cancer.</p> <p>10 Q You would be --</p> <p>11 MR. KLATT: Object. Nonresponsive.</p> <p>12 Sorry.</p> <p>13 BY MS. BRANSCOME:</p> <p>14 Q You would be purely speculating to opine</p> <p>15 that the Taher authors, for example, when they</p> <p>16 used the term "possible" to describe the</p> <p>17 association, they actually meant probable,</p> <p>18 correct?</p> <p>19 MS. PARFITT: Objection. Form.</p> <p>20 THE WITNESS: I didn't say they -- they</p> <p>21 actually -- I meant -- I said that it could</p> <p>22 include probable.</p> <p>23 And so you are -- the sense of your</p> <p>24 question is to suppose or assume that their use of</p> <p>25 the word "possible" excludes the concept of</p>
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<p>1 the way. I'm not -- I'm not assume- -- are you</p> <p>2 assuming that they had in mind the IARC</p> <p>3 classification system and that these two</p> <p>4 categories are mutually exclusive?</p> <p>5 Q My question to you, Dr. Siemiatycki, is</p> <p>6 did any of the authors of the three other</p> <p>7 meta-analyses, Berge, Penninkilampi or Taher,</p> <p>8 conclude in their papers that perineal talc use is</p> <p>9 a probable cause of ovarian cancer?</p> <p>10 MS. PARFITT: Objection. Form. Asked</p> <p>11 and answered.</p> <p>12 THE WITNESS: They did not use that</p> <p>13 word. But I would not infer that they don't think</p> <p>14 it's a probable cause from the write-up of</p> <p>15 their -- from their write-up. It is possible that</p> <p>16 they consider the description of this as a --</p> <p>17 where is the word "possible"? Is that in the</p> <p>18 Conclusion?</p> <p>19 BY MS. BRANSCOME:</p> <p>20 Q It is.</p> <p>21 A Oh, yeah, possible cause.</p> <p>22 You know, they are -- I mean, I can't</p> <p>23 speak for them because I haven't spoken to any of</p> <p>24 them about this, but I don't think they're</p> <p>25 speaking to a legal audience. And the word</p>	<p>1 probable, that they did not think it's -- because</p> <p>2 they used the word "possible," they absolutely</p> <p>3 denied that it's probable. And I -- that's what</p> <p>4 I'm disagreeing with.</p> <p>5 BY MS. BRANSCOME:</p> <p>6 Q Where I'm coming from is not relevant to</p> <p>7 the question that I'm asking, Dr. Siemiatycki.</p> <p>8 The question that I'm asking you is, do any of the</p> <p>9 authors of the three meta-analyses that we just</p> <p>10 reviewed, Berge, Penninkilampi, and Taher,</p> <p>11 describe in their papers the association between</p> <p>12 perineal use of talc and ovarian cancer as a</p> <p>13 probable causal association?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 BY MS. BRANSCOME:</p> <p>16 Q Do any of them use that term?</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: None of them use that</p> <p>19 term, but that doesn't preclude that they -- some</p> <p>20 of them believe it is probable.</p> <p>21 MR. KLATT: Object. Nonresponsive.</p> <p>22 BY MS. BRANSCOME:</p> <p>23 Q You have no basis for concluding or even</p> <p>24 suggesting that any of these authors have the</p> <p>25 opinion that it is a probable causal association</p>

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<p>1 other than speculating based off of what you're</p> <p>2 reading on the page, correct?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: Correct. Nor do I have</p> <p>5 any basis for assuming that they don't think it's</p> <p>6 probable on the basis of what I read.</p> <p>7 BY MS. BRANSCOME:</p> <p>8 Q When you write scientific manuscripts,</p> <p>9 Dr. Siemiatycki, are you careful about your word</p> <p>10 choice, particularly in your conclusion section?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 THE WITNESS: I try to be. I try to be.</p> <p>13 BY MS. BRANSCOME:</p> <p>14 Q Okay. If you could turn to tab 33 in</p> <p>15 your binder.</p> <p>16 Are you familiar with the document that</p> <p>17 is located behind tab 33 in your binder there?</p> <p>18 A I -- I think so. I -- mine had a</p> <p>19 different cover page when I printed it off, but</p> <p>20 that's fine. I'm -- I assume it's the same one</p> <p>21 I -- I had.</p> <p>22 MR. TISI: It's not. It's not.</p> <p>23 MS. PARFITT: What are you referring to?</p> <p>24 MR. TISI: The draft article is not --</p> <p>25 MS. PARFITT: Yeah, I know that.</p>	<p>1 bureau or division. I'm not quite sure.</p> <p>2 Q Okay. And the document that you're</p> <p>3 looking at there is contained within a binder that</p> <p>4 we have previously marked as Exhibit 4, correct?</p> <p>5 A Correct.</p> <p>6 Q All right. Is this an item -- is this</p> <p>7 an item.</p> <p>8 Is this Draft Screening Assessment a</p> <p>9 document that you considered in forming your</p> <p>10 opinions in this case?</p> <p>11 A No, it isn't.</p> <p>12 Q Why not?</p> <p>13 A Because I was only aware of it a month</p> <p>14 or -- a month and a half or two months after I</p> <p>15 completed my report, and two years after I formed</p> <p>16 the main part of my opinion.</p> <p>17 Q How did you obtain a copy of the Draft</p> <p>18 Screening Assessment by Health Canada?</p> <p>19 A I think that this was on the internet.</p> <p>20 I think I --</p> <p>21 THE WITNESS: Yeah, some other -- there</p> <p>22 should be a light button that we can press.</p> <p>23 Excuse me. Excuse me, just maybe off</p> <p>24 the record for a second.</p> <p>25 (A discussion was held off the record.)</p>
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<p>1 THE WITNESS: Is it the Draft Screening</p> <p>2 Assessment?</p> <p>3 MR. TISI: No, that's not the same.</p> <p>4 THE WITNESS: No?</p> <p>5 MR. TISI: It's not.</p> <p>6 MS. PARFITT: Do you have a copy of</p> <p>7 yours?</p> <p>8 THE WITNESS: Yeah.</p> <p>9 MS. BRANSCOME: Can we go off the record</p> <p>10 while we figure this out?</p> <p>11 MS. PARFITT: Sure, that would be fine.</p> <p>12 THE VIDEOGRAPHER: We're going off the</p> <p>13 record at 6:58 p.m.</p> <p>14 (Pause in the proceedings.)</p> <p>15 THE VIDEOGRAPHER: We're back on the</p> <p>16 record at 7:01 p.m.</p> <p>17 BY MS. BRANSCOME:</p> <p>18 Q Dr. Siemiatycki, you have a document in</p> <p>19 front of you that is labeled a "Draft Screening</p> <p>20 Assessment" dated December 2018; is that correct?</p> <p>21 A Yes, I do.</p> <p>22 Q And this is a screening assessment by</p> <p>23 the Environment and Climate Change Canada, Health</p> <p>24 Canada, correct?</p> <p>25 A It's a branch of Health Canada or a</p>	<p>1 THE VIDEOGRAPHER: We are going off the</p> <p>2 record at 7:03 p.m.</p> <p>3 (Pause in the proceedings.)</p> <p>4 THE VIDEOGRAPHER: We are back on the</p> <p>5 record at 7:03 p.m.</p> <p>6 BY MS. BRANSCOME:</p> <p>7 Q Dr. Siemiatycki, we paused because the</p> <p>8 lights turned off, but my question to you is, how</p> <p>9 did you obtain a copy of the Draft Screening</p> <p>10 Assessment by Health Canada?</p> <p>11 A Either it was sent to me by Ms. Parfitt</p> <p>12 or her staff, or I found it on the internet. And</p> <p>13 I can't quite remember now.</p> <p>14 Q Do you remember when you first obtained</p> <p>15 a copy of the Draft Screening Assessment?</p> <p>16 A My guess is just before I went on</p> <p>17 vacation for Christmas and New Years. So it would</p> <p>18 have been mid -- mid to -- mid-December, I guess,</p> <p>19 something like that.</p> <p>20 Q Are you familiar with the process by</p> <p>21 which draft screening assessments are generated by</p> <p>22 Health Canada?</p> <p>23 A No, not really. I was involved with</p> <p>24 this department of Health Canada 30 years ago, and</p> <p>25 I haven't been involved since. I don't know how</p>

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<p>1 they function really to produce these evaluations 2 and reports. 3 Q Did you have any involvement, even 4 tangentially, in the development of the Draft 5 Screening Assessment by Health Canada? 6 A No. 7 Q Were you ever asked to consult on any of 8 the content that ultimately ended up in the Draft 9 Screening Assessment? 10 A No, I wasn't. 11 Q Were you ever contacted about 12 potentially being involved in a Draft Screening 13 Assessment of talc for Health Canada? 14 A No. Never. 15 Q You are aware that this is in fact a 16 draft assessment by Health Canada, correct? 17 MS. PARFITT: Objection. Form. 18 THE WITNESS: I see that's what it says 19 on the cover page. 20 BY MS. BRANSCOME: 21 Q Are you aware of what further steps in 22 the process must be taken before the draft 23 assessment is potentially accepted or modified? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: I'm not familiar with the</p>	<p>1 A Yes. 2 Q Do you believe -- 3 A If I make such a submission, yes. 4 Q Why -- well, first of all, do you think 5 it's important to disclose your involvement in the 6 litigation if you were to submit something for 7 public comment? 8 A Yes, I think it is. 9 Q And why is that? 10 A Because there's a potential conflict of 11 interest, and they should know about it. 12 Q Would you also notify IARC of your role 13 in litigation involving talcum powder products if 14 you submitted something to them to suggest that a 15 formal evaluation of talc be conducted? 16 A Yes, I would. 17 Q Is that for the same reason? 18 A Yes, it is. 19 Q Is the Draft Screening Assessment the 20 type of material that you think it is reliable to 21 base an expert opinion on? 22 MS. PARFITT: Objection. Form. 23 THE WITNESS: An expert opinion about 24 what? 25 BY MS. BRANSCOME:</p>
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<p>1 details, no. 2 BY MS. BRANSCOME: 3 Q What are you familiar with, if not the 4 details? 5 A I remember seeing that there's a public 6 consultation opportunity, and -- so I guess there 7 will be a period of time during which they will 8 accept public recommendations and comments. And I 9 don't know if it's the same committee that will 10 then review all of that or a committee that's 11 higher up on the administrative pecking order. I 12 don't -- I don't know what happens internally. 13 Q Do you intend to submit anything for 14 the -- during the public comment period? 15 A I -- yeah, I hope to do so. I hope to 16 do so. 17 Q What specifically do you intend to 18 submit? 19 A I'm not sure yet. I -- I would probably 20 submit an opinion supporting the notion that 21 perineal use of talc is more likely than not 22 related to ovarian cancer. 23 Q In your submission, do you intend to 24 disclose your role in litigation involving talcum 25 powder products?</p>	<p>1 Q About the potential relationship between 2 talc and ovarian cancer. 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: Are you asking if it would 5 influence my opinion on the issue or -- 6 BY MS. BRANSCOME: 7 Q So under- -- understanding that the 8 Draft Screening Assessment came out after you had 9 formed your opinion, I'm asking you that if that 10 had not been the case, if it had come out while 11 you were still forming your expert opinion, is 12 this something that you would rely on? 13 A I would take cognizance of it, and I'm 14 not sure whether it would persuade me in one 15 direction or another on the strength of the 16 evidence, but it -- it would certainly give me -- 17 increase my comfort level to draw inferences to 18 see what inferences other people draw. I won't 19 necessarily follow their opinions, but I find it 20 useful to know what inferences they would draw 21 from it. 22 Q Is a Draft Screening Assessment the type 23 of report or publication that you see cited in 24 published scientific literature? 25 MS. PARFITT: Objection. Form.</p>

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<p>1 THE WITNESS: Not -- not -- in 2 scientific literature, not so much, no. 3 BY MS. BRANSCOME: 4 Q The draft assessment -- first of all, 5 are you familiar with the proposal with respect to 6 talc that's contained in the draft assessment? 7 A Which proposal are you referring to? 8 Q I could refer you specifically to 9 page -- 10 MR. TISI: I spilled coffee on it too. 11 Sorry. You get what you get. 12 BY MS. BRANSCOME: 13 Q -- on page 29. 14 A The Conclusion section? 15 Q Yes. Have you reviewed this before? 16 A I -- I might have looked at it quickly. 17 But let me -- let me review it -- let me read it 18 now. (Peruses document.) 19 You know, it refers to the fit of the -- 20 their findings and conclusions with various 21 articles of law in the Canadian Environmental 22 Protection Act. I would have to know what those 23 articles of law are that this conforms to, that 24 these sentences purportedly conform to. I -- I 25 have no reason to doubt what they say, but I -- I</p>	<p>1 describing the conclusion as a proposal? Or -- 2 yeah. 3 BY MS. BRANSCOME: 4 Q Focusing specifically on the second 5 paragraph where it says: "It is proposed to 6 conclude that talc meets the criteria under 7 paragraph 64(c) of CEPA as it is entering or may 8 enter the environment in a quantity or 9 concentration or under conditions that constitute 10 or may constitute a danger in Canada to human life 11 or health." 12 MS. PARFITT: Objection. Form. 13 THE WITNESS: It's not a way of 14 describing scientific evidence that I'm intimately 15 familiar with. So I would need to review this 16 document in more detail and be aware of the 17 paragraph 64(c) of the CEPA. 18 BY MS. BRANSCOME: 19 Q And that is not something you -- 20 A So I'm not -- 21 Q -- have done as of today? 22 A It's not something I base -- today I 23 couldn't say I agree with this or I don't agree 24 with this. 25 Q Okay. And so this is not -- the Draft</p>
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<p>1 can't confirm. 2 Q So as you sit here today, are you 3 capable or prepared to offer an opinion as to how 4 the conclusions in the Draft Screening Assessment 5 relate to other pieces of literature that we've 6 discussed today? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: How they relate to -- or 9 whether they're concordant with other pieces? 10 It's difficult for me to say without studying this 11 document more and seeing what the conformity is 12 with the Canadian pieces of legislation that they 13 refer to. So I -- I can't -- I can't give you 14 much more than that. 15 BY MS. BRANSCOME: 16 Q So as you sit here today, could you -- 17 do you have an opinion as to how the proposal in 18 the Draft Screening Assessment with respect to 19 talc relates to the current IARC classification of 20 talc? 21 MS. PARFITT: Objection. Form. 22 THE WITNESS: By proposal, you mean the 23 conclusion? 24 MS. PARFITT: The entire document. 25 THE WITNESS: You're -- you're</p>	<p>1 Screening Assessment by Health Canada is not 2 something that you are relying upon in any way in 3 offering your expert opinions in this case; is 4 that correct? 5 MS. PARFITT: Objection. Form, 6 misstates his testimony. 7 THE WITNESS: No. As I said, I didn't 8 rely on this to form my opinion. 9 BY MS. BRANSCOME: 10 Q Okay. 11 MS. BRANSCOME: Could we go off the 12 record just briefly? 13 MS. PARFITT: Of course. 14 THE VIDEOGRAPHER: We're going off the 15 record at 7:15 p.m. 16 (Pause in the proceedings.) 17 THE VIDEOGRAPHER: We're back on the 18 record at 7:16 p.m. 19 BY MS. BRANSCOME: 20 Q Dr. Siemiatycki, can you describe -- can 21 you identify for me specifically the pieces of 22 evidence that you would cite to in support of your 23 opinion that there is evidence consistent with a 24 dose-response relationship that was not considered 25 by the IARC 2006 working group?</p>

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<p>1 A Can --</p> <p>2 Q And I'm just looking for an</p> <p>3 identification of the papers.</p> <p>4 A Let me just dig out -- I keep hiding</p> <p>5 things from myself.</p> <p>6 MS. PARFITT: Okay.</p> <p>7 THE WITNESS: Oh, there.</p> <p>8 The primary pieces of evidence -- the</p> <p>9 primary piece of evidence is the analysis carried</p> <p>10 out in the Terry, et al., paper where they</p> <p>11 combined ten different studies from eight</p> <p>12 different research teams. They had by far the</p> <p>13 largest sample size of any conglomeration of</p> <p>14 studies ever conducted, enough to properly</p> <p>15 evaluate dose-response. And that's one of them.</p> <p>16 The second one is the Schildkraut study,</p> <p>17 which is much smaller than the Terry study in</p> <p>18 terms of numbers.</p> <p>19 And the third -- a third one, which was</p> <p>20 not part of the evidence that influenced my</p> <p>21 evaluation, is the latest version of the Berge</p> <p>22 paper which has some dose-response results in a</p> <p>23 table whose origin I don't completely understand,</p> <p>24 but ostensibly it gives dose-response trends that</p> <p>25 are significant and meaningful for duration and</p>	<p>1 use your own copy if that's more convenient.</p> <p>2 A Yep. There we go. Okay.</p> <p>3 Q Did the authors of the Terry 2013 paper,</p> <p>4 did they conclude in their manuscript that they</p> <p>5 had observed a statistically significant dose-</p> <p>6 response relationship between the perineal use of</p> <p>7 talc and ovarian cancer?</p> <p>8 A They reported two different ways of</p> <p>9 calculating the statistical significance of a</p> <p>10 trend. One of them was significant, and the other</p> <p>11 was formal, in terms of the conventional 0.05</p> <p>12 statistical significance level, was not</p> <p>13 significant at that level.</p> <p>14 Q And in fact in the abstract, the authors</p> <p>15 of the Terry paper state that: "Among genital</p> <p>16 powder users, we observed no significant trend,</p> <p>17 p equals 0.17, in risk with increasing number of</p> <p>18 lifetime applications," in parentheses, "assessed</p> <p>19 in quartiles."</p> <p>20 Did I read that correctly?</p> <p>21 A That's correct.</p> <p>22 Q Okay. Now, in your 2016 report --</p> <p>23 A Yeah.</p> <p>24 Q -- you had the statement that: "The</p> <p>25 appropriate statistical test for trend is one that</p>
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<p>1 frequency of exposure. But I would put less</p> <p>2 weight on that until I fully understand what --</p> <p>3 how they derived those estimates.</p> <p>4 BY MS. BRANSCOME:</p> <p>5 Q Okay. So the pieces of evidence that</p> <p>6 you would cite to in support of the idea that</p> <p>7 there has been a development that is supportive of</p> <p>8 a dose-response relationship between perineal talc</p> <p>9 and ovarian cancer since the IARC classification</p> <p>10 of talc as a 2B would be the Terry, the</p> <p>11 Schildkraut, and potentially the Berge analysis;</p> <p>12 is that correct?</p> <p>13 MS. PARFITT: Objection --</p> <p>14 THE WITNESS: Yes.</p> <p>15 MS. PARFITT: -- to the reference of</p> <p>16 "potentially the Berge." Form.</p> <p>17 BY MS. BRANSCOME:</p> <p>18 Q You did not rely in any way on the</p> <p>19 analysis in the Berge 2018 paper for your</p> <p>20 conclusion that there is evidence compatible with</p> <p>21 a dose-response relationship between perineal talc</p> <p>22 use and ovarian cancer, correct?</p> <p>23 A That's correct.</p> <p>24 Q Okay. So looking first at the Terry</p> <p>25 2013 paper. This is tab 14 or you're welcome to</p>	<p>1 excludes the baseline unexposed category."</p> <p>2 Do you remember having that sentence in</p> <p>3 your 2016 report?</p> <p>4 A I remember the -- the idea being there,</p> <p>5 yes.</p> <p>6 Q Okay. And you would agree that if you</p> <p>7 apply that statistical test for trend, meaning you</p> <p>8 exclude the baseline unexposed category, the Terry</p> <p>9 2013 paper does not demonstrate a dose-response</p> <p>10 relationship, correct?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: No.</p> <p>13 MS. PARFITT: Misstates testimony.</p> <p>14 THE WITNESS: So I would not conclude --</p> <p>15 I would say that it demonstrates dose-response,</p> <p>16 but not at a statistical -- at a 0.05 statistical</p> <p>17 significance level.</p> <p>18 And I would also -- I can't remember the</p> <p>19 wording and the context in the 2016 report that</p> <p>20 you're referring to, but I would imagine that I</p> <p>21 preceded that statement with some mention of the</p> <p>22 fact that it depends if you are using the overall</p> <p>23 risk among all exposed people compared to</p> <p>24 unexposed people as a complementary piece of</p> <p>25 information.</p>

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<p>1 And it's only in the context when you 2 are using the -- all the exposed compared to all 3 the unexposed, and at the same time carrying out 4 an analysis of the different levels of exposure, 5 that including the unexposed among the -- in that 6 trend analysis becomes overlapping information 7 with the overall -- the significance of the 8 overall estimate. 9 BY MS. BRANSCOME: 10 Q Okay. 11 A This -- I'm not quite finished. Sorry. 12 So -- and because I don't want you to 13 think that I believe or believed that on its own 14 there is no evidence of dose-response. There is 15 evidence of dose-response in the Terry analysis. 16 The choice of which p-value to report on the trend 17 analysis depends completely on how one combines 18 that information with the ever exposed/never 19 exposed information and the p-value for that. 20 That when we want completely independent and 21 separate strands of evidence to corroborate each 22 other, then it's appropriate to exclude the 23 unexposed from the p-value computation. 24 When you are using -- when you are not 25 using the binary exposed/unexposed as part of the</p>	<p>1 are you positing? 2 BY MS. BRANSCOME: 3 Q Of those ten studies, which, if any of 4 them, postdate 2006? Do you know? 5 A Most of them do. I would say -- I think 6 the only one -- ones that were published before 7 2006 were a study by Chang and one or two of the 8 components of Cramer's studies. I think the rest 9 were all published post-2006. 10 Q Okay. Did you independently do an 11 analysis of the potential dose-response 12 relationship of perineal talc use and ovarian 13 cancer? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: By "independently," you 16 mean trying to replicate the Terry analysis? No. 17 I don't see why I would be motivated to do 18 something that someone else has already done. 19 BY MS. BRANSCOME: 20 Q Okay. So you are relying on the data as 21 reported by Terry 2013 that you consider to be 22 evidence in support of a dose-response 23 relationship, correct? 24 A That's correct. 25 Q Okay. But the authors themselves do not</p>
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<p>1 package of information to demonstrate causation, 2 then the correct p-value is the one that includes 3 the unexposed. So it depends how you use these 4 things. 5 If I didn't qualify that statement that 6 you read before, then I was in error. 7 Q If you did not have the Terry 2013 8 study -- 9 A Yes. 10 Q -- set that aside for a moment, you did 11 not have that data, would it still be your opinion 12 that the perineal use of talc probably causes 13 ovarian cancer? 14 A So -- 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: So just to be clear what 17 the hypothetical supposition is, so the Terry 18 paper doesn't exist, but the studies underlying 19 the Terry paper still do exist, correct? Or they 20 don't exist either? 21 So there are ten studies underlying the 22 Terry reanalysis. Is your hypothetical question 23 about the possibility that none of those studies 24 existed or that they existed, but nobody actually 25 put them together to combine an analysis? What</p>	<p>1 conclude that there has been a statistically 2 significant dose-response relationship established 3 for the perineal use of talc and ovarian cancer, 4 correct? 5 MS. PARFITT: Objection. Form, 6 misstates the evidence. 7 THE WITNESS: I -- I didn't review what 8 they concluded in the Discussion section. If you 9 want, I could review that. And I -- I don't 10 remember what -- what kind of narrative inferences 11 they made about it. 12 BY MS. BRANSCOME: 13 Q Okay. 14 A You're asking me to confirm that they 15 didn't conclude, so I would want -- their data in 16 my mind indicates dose-response. How they 17 interpret it -- as I said before, they're two 18 separate things, the production of findings from 19 research and the interpretation of those findings. 20 I am as capable of interpreting -- they 21 aren't as capable of interpreting my findings from 22 my studies as I am or they are as capable -- they 23 have the right to. I have the right to interpret 24 their findings. It's a different activity 25 producing findings and then interpreting them. So</p>

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<p>1 how they interpreted their findings, I don't quite 2 remember exactly what they said about it. 3 Q Okay. 4 MS. BRANSCOME: I am going to pass to 5 counsel for Imerys at this time. 6 MR. KLATT: Can we go off the record for 7 just a couple of minutes? Let me get organized. 8 THE VIDEOGRAPHER: We are going off the 9 record at 7:31 p.m. 10 (Pause in the proceedings.) 11 THE VIDEOGRAPHER: We are going back on 12 the record at 7:32 p.m. 13 DIRECT EXAMINATION 14 BY MR. KLATT: 15 Q Good afternoon -- good evening, 16 Dr. Siemiatycki. 17 A Good evening. How are you? 18 Q I'm Mike Klatt. I represent Imerys Talc 19 America in this case. 20 I don't know if you recall or not, but 21 you and I had met about two years ago when you 22 were giving a deposition in the Oules and Swan 23 cases. Do you recall that? 24 A I do recall that. 25 Q Okay.</p>	<p>1 people at IARC and the public generally to know 2 that you had been a retained and paid expert by 3 plaintiffs' counsel in the talc ovarian cancer 4 litigation; is that correct? 5 A Sir, can you -- I think I already said 6 that, but could you repeat? Maybe I'm 7 misunderstanding. 8 Q Yes. I'm just saying such a conflict of 9 interest disclosure on your part, it would be 10 important to disclose not merely that you had been 11 a consultant or merely that you had been involved 12 in litigation involving ovarian cancer, but it 13 would be important to specifically disclose that 14 you had been a retained and paid expert by 15 plaintiffs' counsel in the talc/ovarian cancer 16 litigation. Correct? 17 MS. PARFITT: Objection. Form, asked 18 and answered. 19 THE WITNESS: I -- I'm not sure I 20 understand the distinction between this last 21 affirmation and the one before. I -- yes, it -- 22 BY MR. KLATT: 23 Q Well, we've had -- we've had other 24 conflict of interest disclosures, and I put that 25 in quotes, where people said that they had been a</p>
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<p>1 A Very fondly. 2 Q Thank you. 3 I just have a few questions for you, and 4 I want to go back and just make sure the record is 5 clear on something. 6 Your testimony is you've had no contact 7 or communications whatsoever with anyone with 8 Health Canada regarding talc; is that correct? 9 A That's correct. 10 Q And you've had no contact or 11 communications whatsoever with Dr. Krewski or 12 anyone else who's an author of the Taher 13 meta-analysis regarding talc? 14 A That's correct. 15 Q That's correct. Okay. 16 A minute ago I believe you told 17 Ms. Branscome that if you continued to interact 18 with IARC or have contact with Health Canada 19 regarding the issue of talc and ovarian cancer, 20 it's incumbent upon you to have a conflict of 21 interest disclosure, correct? 22 A Yes. I said that. 23 Q And you would agree with me it would be 24 important in evaluating any potential bias you 25 have for the people at Health Canada and the</p>	<p>1 consultant, period. That wouldn't be sufficient, 2 would it? 3 A I would -- 4 MS. PARFITT: Objection. Form. 5 THE WITNESS: I would not do that. 6 BY MR. KLATT: 7 Q And we've had people say, I've been 8 involved as an expert in ovarian cancer 9 litigation. That wouldn't be sufficient either, 10 correct? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: I would not do that. 13 BY MR. KLATT: 14 Q What you would do is you would say, I 15 have been a retained and paid expert by 16 plaintiffs' counsel in the talc/ovarian cancer 17 lawsuits, or something essentially equivalent to 18 that. 19 A I -- I would say something essentially 20 equivalent. It's quite possible that if there was 21 a submission to a journal, for example, or a 22 manuscript, the journal may have a formulaic way 23 of expressing that. So... 24 Q But wouldn't it be important to the 25 readers to know which side of the litigation you</p>

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<p style="text-align: right;">Page 278</p> <p>1 had been on in evaluating your bias?</p> <p>2 MS. PARFITT: Objection. Form, asked</p> <p>3 and answered.</p> <p>4 THE WITNESS: I -- I would -- I would</p> <p>5 disclose the nature of my involvement.</p> <p>6 BY MR. KLATT:</p> <p>7 Q Including which side?</p> <p>8 A Including which side I was consulting</p> <p>9 for.</p> <p>10 Q Okay.</p> <p>11 MR. KLATT: Can we mark this as the next</p> <p>12 exhibit?</p> <p>13 MS. PARFITT: 14.</p> <p>14 (Exhibit No. 14 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. KLATT:</p> <p>17 Q Dr. Siemiatycki, you said earlier that</p> <p>18 you worked with Dr. Koushik; is that correct?</p> <p>19 A Yes.</p> <p>20 Q And what is your professional</p> <p>21 relationship with Dr. Koushik?</p> <p>22 A We are members of the same academic</p> <p>23 department. We are down the hall from each other.</p> <p>24 Our offices are nearby each other. We have worked</p> <p>25 together on various projects.</p>	<p style="text-align: right;">Page 280</p> <p>1 PROVAQ study, correct?</p> <p>2 A Correct.</p> <p>3 Q And that's the study she is working on</p> <p>4 with you, correct?</p> <p>5 A More I'm working on with her, but she's</p> <p>6 the lead on that.</p> <p>7 Q And with the help of others in your</p> <p>8 group as well --</p> <p>9 A With the help of others, yes.</p> <p>10 Q -- correct?</p> <p>11 And what I've handed you --</p> <p>12 MR. KLATT: And what was the exhibit</p> <p>13 number?</p> <p>14 MR. TISI: 14.</p> <p>15 BY MR. KLATT:</p> <p>16 Q Exhibit 14 is Dr. Koushik's web pages</p> <p>17 from the Environ Epi website. You're familiar</p> <p>18 with that website, correct?</p> <p>19 A Yes, I am.</p> <p>20 Q And you'll turn to the back page of the</p> <p>21 exhibit, the final page, and you will see it's</p> <p>22 copyrighted 2019, correct?</p> <p>23 A Correct.</p> <p>24 Q And let's just see what Dr. Koushik says</p> <p>25 about her research on the first page. She says:</p>
<p style="text-align: right;">Page 279</p> <p>1 Q For how long?</p> <p>2 A Ten -- 10 or 12 years now.</p> <p>3 Q And she's very well educated, correct?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 THE WITNESS: I'm not sure what you mean</p> <p>6 by that. She has a --</p> <p>7 BY MR. KLATT:</p> <p>8 Q Well, she has a Bachelor --</p> <p>9 A She has a --</p> <p>10 Q -- of Science in pharmacology from the</p> <p>11 University of Alberta.</p> <p>12 A Correct.</p> <p>13 Q She has a Master's in community health</p> <p>14 and epidemiological from Queen's University in</p> <p>15 Kingston, Ontario?</p> <p>16 A Uh-huh.</p> <p>17 Q She has a Ph.D. in epidemiology from --</p> <p>18 in epidemiology and biostatistics from McGill</p> <p>19 University here in Montreal, correct?</p> <p>20 A Correct.</p> <p>21 Q And she's had a postdoctoral fellowship</p> <p>22 at Harvard in the U.S., correct?</p> <p>23 A Correct.</p> <p>24 Q And she is the principal investigator of</p> <p>25 the Prevention of Ovarian Cancer in Quebec, the</p>	<p style="text-align: right;">Page 281</p> <p>1 "My research program focuses on the epidemiology</p> <p>2 of ovarian and lung cancers." Correct?</p> <p>3 A Mm-hmm, yes.</p> <p>4 Q "Ovarian cancer is by far the most</p> <p>5 deadly of all gynecologic cancer. Most patients</p> <p>6 are diagnosed at advanced stages, leading to the</p> <p>7 poor prognosis, and we are currently limited in</p> <p>8 our ability to detect disease early." Correct?</p> <p>9 A Correct.</p> <p>10 Q She says: "There is overwhelming</p> <p>11 evidence that healthy lifestyle choices can reduce</p> <p>12 the risk of several cancers. However, we do not</p> <p>13 yet know of any effective ways to prevent the</p> <p>14 onset of ovarian cancer."</p> <p>15 Would you agree with that?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 THE WITNESS: I'm sorry, I'm trying to</p> <p>18 think of what this sentence really means. It's</p> <p>19 kind of a -- it's kind of a stock sentence that is</p> <p>20 used in -- by epidemiologists when they're looking</p> <p>21 for funding and trying to convince funders that</p> <p>22 we don't know a lot, and therefore they need to</p> <p>23 give us money. So I can imagine part of this is</p> <p>24 cut-and-pasted from that sort of document.</p> <p>25 BY MR. KLATT:</p>

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<p>1 Q Well, what it means is --</p> <p>2 MS. PARFITT: Wait, wait. Please let</p> <p>3 him finish.</p> <p>4 BY MR. KLATT:</p> <p>5 Q Go ahead.</p> <p>6 MS. PARFITT: Thanks, Mike.</p> <p>7 THE WITNESS: There are some risk</p> <p>8 factors that are well established for -- for</p> <p>9 ovarian cancer, which Anita is very well aware of,</p> <p>10 genetic and certain reproductive and hormonal</p> <p>11 factors.</p> <p>12 The evidence on talc is accumulating,</p> <p>13 and in my view is sufficient. Anita has not</p> <p>14 reviewed that evidence. And --</p> <p>15 BY MR. KLATT:</p> <p>16 Q Have you talked to Dr. Koushik at all</p> <p>17 about your involvement in the talc ovarian cancer</p> <p>18 litigation?</p> <p>19 A She's aware that I'm involved in this.</p> <p>20 Q Well, let's go on to see what she says</p> <p>21 here.</p> <p>22 After saying: "However, we do not yet</p> <p>23 know of any effective ways to prevent the onset of</p> <p>24 ovarian cancer," she says, "the evidence on some</p> <p>25 lifestyle factors, such as alcohol intake,</p>	<p>1 intake, and recreational physical activity."</p> <p>2 Correct?</p> <p>3 A Correct.</p> <p>4 Q She doesn't say a word about talc there,</p> <p>5 does she?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 THE WITNESS: She doesn't there because</p> <p>8 she hasn't started those analyses yet. She has</p> <p>9 started analyses -- or her -- with students on</p> <p>10 those other factors.</p> <p>11 BY MR. KLATT:</p> <p>12 Q And then flipping over to the next page,</p> <p>13 Dr. Koushik says: "Healthy lifestyle choices may</p> <p>14 also positively impact the health of ovarian</p> <p>15 cancer survivors. Indeed, until we know how to</p> <p>16 prevent ovarian cancers from occurring in the</p> <p>17 first place, cancer control through tertiary</p> <p>18 prevention aimed at improving prognosis and</p> <p>19 quality of life among those diagnosed is</p> <p>20 critical." Correct?</p> <p>21 A Correct.</p> <p>22 Q And again, no mention at all of talc,</p> <p>23 correct?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: Correct.</p>
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<p>1 physical activity, and smoking, is suggestive but</p> <p>2 currently remains unclear." Correct?</p> <p>3 A Correct.</p> <p>4 Q She doesn't say one word about talc,</p> <p>5 does she?</p> <p>6 A No.</p> <p>7 MS. PARFITT: Objection. Form.</p> <p>8 THE WITNESS: Not here, no.</p> <p>9 BY MR. KLATT:</p> <p>10 Q And then she goes on to say: "More</p> <p>11 research is greatly needed, especially in light of</p> <p>12 recent discoveries that demonstrate that ovarian</p> <p>13 cancer is a heterogeneous disease." She says: "I</p> <p>14 am the principal investigator of the Prevention of</p> <p>15 Ovarian Cancer in Quebec, PROVAQ study, a</p> <p>16 population-based case-control study conducted in</p> <p>17 2011, 2016."</p> <p>18 And one of the things she's evaluating</p> <p>19 in that study is talc, correct?</p> <p>20 A Correct.</p> <p>21 Q "This study provides" -- and I'm reading</p> <p>22 on -- "This study provides a rich data source for</p> <p>23 the study of multiple hypotheses on lifestyle</p> <p>24 factors and ovarian cancer. Current projects</p> <p>25 focus on associations with shift work, caffeine</p>	<p>1 MR. KLATT: Let's mark that.</p> <p>2 MS. PARFITT: This is now 15.</p> <p>3 MR. KLATT: Have we marked that?</p> <p>4 MS. PARFITT: I just now did. I was</p> <p>5 looking for the stickers. I'm going to get one --</p> <p>6 here they are.</p> <p>7 THE WITNESS: I have a different cover.</p> <p>8 MS. PARFITT: It's a different one.</p> <p>9 That's yours.</p> <p>10 THE WITNESS: Oh.</p> <p>11 MS. PARFITT: This is different, this is</p> <p>12 a new item. Let me just put an exhibit on this</p> <p>13 one.</p> <p>14 (Exhibit No. 15 was marked for</p> <p>15 identification.)</p> <p>16 MS. PARFITT: Thank you.</p> <p>17 Okay. You're done with this. And he's</p> <p>18 just showing you this one.</p> <p>19 Do we have an extra copy, Mike, or is</p> <p>20 this it?</p> <p>21 MR. KLATT: I've got an extra copy if</p> <p>22 you need it.</p> <p>23 MS. PARFITT: Okay, that would be great.</p> <p>24 I will give him that one. Thank you very much.</p> <p>25 BY MR. KLATT:</p>

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<p>1 Q So, Dr. Siemiatycki, I'm now showing you</p> <p>2 what we marked as exhibit -- what?</p> <p>3 MS. PARFITT: 15.</p> <p>4 MR. KLATT: 15?</p> <p>5 MS. PARFITT: Yes.</p> <p>6 BY MR. KLATT:</p> <p>7 Q And it's from the Environ Epi website,</p> <p>8 your website, and it's the web pages discussing</p> <p>9 group research topics, correct?</p> <p>10 A I -- I have to tell you I don't look at</p> <p>11 this website, and I haven't actually constituted</p> <p>12 it. It's my secretary or my assistant who does</p> <p>13 this. So I'm looking at it afresh to see what's</p> <p>14 there. Yeah.</p> <p>15 Q Okay. Let's -- let's turn to the very</p> <p>16 back page, and again the copyright is 2019.</p> <p>17 That's this year, correct?</p> <p>18 A Yeah. Yes.</p> <p>19 Q And then if you will flip over to --</p> <p>20 let's see. Well, let's start -- let's see.</p> <p>21 Go first page, second page, third</p> <p>22 page -- the fourth page, there's a discussion</p> <p>23 there of the PROVAQ study of Dr. Koushik that we</p> <p>24 just talked about, correct?</p> <p>25 A Yes.</p>	<p>1 reproductive factors is limited. There is</p> <p>2 suggestive evidence that modifiable factors in the</p> <p>3 vitamin D pathway, (sun exposure, diet), and</p> <p>4 inflammation pathway (antiinflammatory medication</p> <p>5 use, talc use for feminine hygiene) may play a</p> <p>6 role in ovarian cancer risk, though this research</p> <p>7 has been limited by small sample sizes, crude</p> <p>8 exposure measurement and lack of control for</p> <p>9 important confounders." Correct?</p> <p>10 A That's what it says.</p> <p>11 Q Did I read that correctly?</p> <p>12 A Yes, you did.</p> <p>13 Q So on this public website, your</p> <p>14 Environmental Epi website, Dr. Jack Siemiatycki</p> <p>15 doesn't say talc use causes ovarian cancer,</p> <p>16 correct?</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: I don't say anything on</p> <p>19 that website.</p> <p>20 BY MR. KLATT:</p> <p>21 Q Well, you -- your group doesn't say talc</p> <p>22 causes ovarian cancer, does it?</p> <p>23 MR. TISI: Objection. Form.</p> <p>24 THE WITNESS: In my opinion, this was</p> <p>25 created somewhere around 2009, 2010, 2012, in that</p>
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<p>1 Q And the topic says: "Prevention of</p> <p>2 Ovarian Cancer in Quebec, the PROVAQ study, a</p> <p>3 case-control study of modifiable and genetic</p> <p>4 factors associated with the risk of ovarian</p> <p>5 cancer." Correct?</p> <p>6 A I see that.</p> <p>7 Q And it says Anita Koushik, that's</p> <p>8 Dr. Koushik, who we've just been talking about,</p> <p>9 and it says Jack Siemiatycki. That's you,</p> <p>10 correct?</p> <p>11 A That's right.</p> <p>12 Q And then it goes on to describe what the</p> <p>13 PROVAQ study is, and it says -- and I'll skip the</p> <p>14 first few sentences -- it says: "Primary</p> <p>15 prevention thus offers the most promising approach</p> <p>16 to reducing the morbidity and mortality associated</p> <p>17 with this deadly disease. Established preventive</p> <p>18 factors for ovarian cancer include high parity,</p> <p>19 long duration of lactation, oral contraceptive</p> <p>20 use, and tubal ligation." Correct?</p> <p>21 A That's what it says.</p> <p>22 Q Talc is not included in that list of</p> <p>23 established preventive factors, is it?</p> <p>24 A It's not listed there, no.</p> <p>25 Q "However, the ability to modify these</p>	<p>1 ballpark. This feels to me like a cut and paste</p> <p>2 from the grant application of 2009 or 2010 that</p> <p>3 hasn't been changed.</p> <p>4 There's not really a lot of motivation</p> <p>5 for us to -- besides just sort of putting our</p> <p>6 names and faces up there, our institution asks us</p> <p>7 to put something on this institutional website</p> <p>8 for a researcher. I haven't -- I've never looked</p> <p>9 at this.</p> <p>10 BY MR. KLATT:</p> <p>11 Q You or your organization --</p> <p>12 MS. PARFITT: Wait. Mike -- Mike,</p> <p>13 excuse me, I think we're done.</p> <p>14 THE WITNESS: I've never contributed to</p> <p>15 this or looked at it.</p> <p>16 MS. PARFITT: No, no, Mike,</p> <p>17 unfortunately, your time is up.</p> <p>18 MR. KLATT: You've --</p> <p>19 MS. PARFITT: Mike, no more questions.</p> <p>20 I have a few questions. I think we're --</p> <p>21 MR. KLATT: Are we -- are we done?</p> <p>22 THE VIDEOGRAPHER: Yes.</p> <p>23 MR. KLATT: All right.</p> <p>24 MS. PARFITT: Thank you. I do have a</p> <p>25 few.</p>

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<p>1 Dr. Siemiatycki, I'm going to stay right 2 over here for a moment, okay? And we can get 3 through this. Okay? 4 MR. KLATT: Here, I'll give this back to 5 you. 6 THE WITNESS: Hi. 7 MS. PARFITT: Tell me when you are 8 ready. 9 THE WITNESS: Who are you? 10 MS. PARFITT: I know. 11 MR. TISI: Are we back on? Are we back 12 on? 13 THE VIDEOGRAPHER: I didn't stop. 14 Sorry, I -- 15 MR. TISI: Oh, I thought we were off. 16 MS. PARFITT: Okay. We didn't -- we 17 didn't know that. 18 CROSS-EXAMINATION 19 BY MS. PARFITT: 20 Q Dr. Siemiatycki, good evening -- 21 Okay. Dr. Siemiatycki, good evening. I 22 know it's been a long day, and I have a few 23 questions, and I will be wrapping -- or jumping 24 around a bit, so hopefully try and keep pace with 25 me, and I'll try and speak slowly and -- so that</p>	<p>1 MS. BRANSCOME: Objection. 2 THE WITNESS: I think it was ordered -- 3 it was contracted in order to underpin the Health 4 Canada evaluation. That's my -- 5 BY MS. PARFITT: 6 Q All right. Now, it was not the only 7 study or research that was conducted by Health 8 Canada; is that correct? It was the meta-analysis 9 that was conducted by them. 10 MS. BRANSCOME: Objection. 11 THE WITNESS: Sorry, I -- what -- 12 BY MS. PARFITT: 13 Q The Taher study -- 14 A Study. 15 Q -- is a meta-analysis; is that correct? 16 A Yes. Yes. 17 Q All right. And the Taher meta-analysis 18 was one part of the information that formulated 19 part of the Health Canada draft assessment? 20 A That's my understanding, yes. 21 Q All right. Now, Daniel Krewski, you 22 indicated, was one of the authors of the Taher 23 paper. 24 A Yes. He's listed. 25 Q And I believe you testified that you</p>
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<p>1 we can move through the remainder of your 2 deposition. 3 Dr. Siemiatycki, do you have an opinion 4 as to whether the elimination of talcum powder use 5 in the genital area is a lifestyle activity that 6 is modifiable? 7 If you need me to ask the question 8 again, I'm happy to. 9 A Yeah, I'm trying to think of how the 10 word "modifiable" is used. 11 Q Is it preventable? Is the use of talcum 12 powder products in the genital area a preventable 13 activity? 14 A Yes. 15 MS. BRANSCOME: Objection. 16 BY MS. PARFITT: 17 Q All right. Thank you. 18 All right. You were asked some 19 questions about the Taher article. You remember 20 that? 21 A Yes. 22 Q All right. And is it your understanding 23 that the Taher article is a meta-analysis that was 24 formed as part of the Health Canada 25 recommendation?</p>	<p>1 know Daniel Krewski. 2 A Yes, I do. 3 Q And I believe Mr. Klatt asked you 4 whether or not you had reached out or perhaps 5 Ms. Branscome asked you whether or not you have 6 had any communication with anyone, verbal, oral, 7 written, that had anything to do with Health 8 Canada. Do you remember that? 9 A Yes, I do remember. 10 Q All right. And it's been many hours, 11 but it was my understanding in response to that 12 question, you did indicate that you had sent an 13 e-mail to Daniel Krewski; is that correct? 14 MS. BRANSCOME: Objection. 15 THE WITNESS: I don't remember saying 16 that. 17 BY MS. PARFITT: 18 Q Okay, let me ask you. Have you ever 19 reached out to any member or author of the Taher 20 meta-analysis? 21 A I -- when I learned about it, I sent an 22 e-mail to Dan Krewski asking if this report was 23 intended for publication; and if so, when it would 24 appear, and I haven't -- I didn't have any 25 response.</p>

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<p>1 Q All right. So you have had no</p> <p>2 communication with any of the authors of the Taher</p> <p>3 study or any of the members of Health Canada?</p> <p>4 A No.</p> <p>5 Q Okay. Now, you were asked some</p> <p>6 questions with regard to the Schildkraut study in</p> <p>7 particular. Now, what I'd like you to do is, if</p> <p>8 you can get that in front of you, and I believe</p> <p>9 it's part of the documentation in your binder,</p> <p>10 number 4.</p> <p>11 And what I'd ask you to also do, if you</p> <p>12 will, is pull out your paper, your Terry paper --</p> <p>13 your copy of the Terry paper, and maybe we'll go</p> <p>14 there first.</p> <p>15 A Terry?</p> <p>16 Q If you get the Terry. Do you have the</p> <p>17 Terry in front of you?</p> <p>18 A Yeah, I've got it in front of me, yes.</p> <p>19 Q Okay. Now, Ms. Branscome asked you and</p> <p>20 referred you to the abstract of the Terry paper.</p> <p>21 Do you recall that --</p> <p>22 A Yes.</p> <p>23 Q -- examination?</p> <p>24 A Yes.</p> <p>25 Q And I believe she focused your attention</p>	<p>1 you?</p> <p>2 A Yes, I do.</p> <p>3 Q And I believe it's a continuation of the</p> <p>4 Results section --</p> <p>5 A Yes.</p> <p>6 Q -- which starts on 815 and continues all</p> <p>7 the way over to the end of the document. Do you</p> <p>8 see that?</p> <p>9 A I do.</p> <p>10 Q All right. And specifically about</p> <p>11 halfway down on page 817 of the Results section of</p> <p>12 the Terry paper, what did the authors find as it</p> <p>13 pertains to whether or not there is evidence</p> <p>14 demonstrating dose-response as it relates to</p> <p>15 genital powder use and ovarian cancer?</p> <p>16 A So are you referring to the sentence</p> <p>17 that begins "Although a significant increase"?</p> <p>18 Q Correct.</p> <p>19 A Or before that?</p> <p>20 Q Whatever you need to read, but I was</p> <p>21 specifically --</p> <p>22 A Okay.</p> <p>23 Q -- referring to the "although." And you</p> <p>24 can read that paragraph, please.</p> <p>25 A Okay. So I'll start at the beginning of</p>
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<p>1 on the very last sentence of the Terry paper, the</p> <p>2 next to last sentence which started with "Among</p> <p>3 genital powder users."</p> <p>4 Do you see that?</p> <p>5 A I see that.</p> <p>6 Q All right. And she asked you whether or</p> <p>7 not indeed the abstract section of the Terry paper</p> <p>8 said: "Among genital powder users, we observed no</p> <p>9 significant trend, p equals 0.17, in risk with</p> <p>10 increasing numbers of lifetime applications</p> <p>11 (assessed in quartiles)."</p> <p>12 A I see that.</p> <p>13 Q All right. You've had an opportunity to</p> <p>14 read this --</p> <p>15 A I've read it --</p> <p>16 Q -- article?</p> <p>17 A -- several times over the last three</p> <p>18 years.</p> <p>19 Q All right. Let me direct your attention</p> <p>20 to the actual paper, and specifically to -- not</p> <p>21 the abstract of the paper but to the section</p> <p>22 that's entitled -- I believe it's the Discussion</p> <p>23 section and it's over on page 817.</p> <p>24 A Yes.</p> <p>25 Q All right. Do you have that in front of</p>	<p>1 that paragraph.</p> <p>2 Q Please, if you will.</p> <p>3 A Read out loud?</p> <p>4 Q If you will.</p> <p>5 A "We evaluated cumulative genital powder</p> <p>6 exposure as a composite variable of frequency and</p> <p>7 duration of use. We have observed similar</p> <p>8 increased risks of all nonmucinous subtypes of</p> <p>9 epithelial ovarian cancer combined across</p> <p>10 quartiles of genital powder compared with nonuse."</p> <p>11 The OR in the first quartile is 1.18 with</p> <p>12 confidence intervals. In the second quartile, it</p> <p>13 was 1.22. In the third quartile, it's 1.22. And</p> <p>14 the fourth quartile it's 1.37.</p> <p>15 I didn't read the confidence intervals.</p> <p>16 Q Are the confidence intervals for the</p> <p>17 quartiles you just discussed all statistically</p> <p>18 significant?</p> <p>19 A Yes, they are.</p> <p>20 Q All right. Please continue.</p> <p>21 A "Although a significant increase in risk</p> <p>22 with an increasing number of genital powder</p> <p>23 applications was found for nonmucinous epithelial</p> <p>24 ovarian cancer when nonusers were included in the</p> <p>25 analysis with a p-value that's extremely small,"</p>

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<p>1 highly significant, "no trend in cumulative use</p> <p>2 was evident in analyses restricted to ever users</p> <p>3 of genital powder for trend .17. Taken together,</p> <p>4 these observations suggest that the significant</p> <p>5 trend test largely reflects the comparison of ever</p> <p>6 regular use with never use."</p> <p>7 Q Okay, and if you would stop there.</p> <p>8 What is the significance of the findings</p> <p>9 of the authors in that paragraph you just read as</p> <p>10 it pertains to whether or not this study shows a</p> <p>11 dose-response increase?</p> <p>12 A Well, so my interpretation is that</p> <p>13 overall there is, for users compared to nonusers,</p> <p>14 a highly significant trend, and four -- among the</p> <p>15 four - there are four quartiles, and there is a</p> <p>16 fifth group called nonusers -- they have a</p> <p>17 relative risk of 1.0. And in those five groups,</p> <p>18 the relative risk -- the relative risk estimates</p> <p>19 go from 1.0 to 1.18 to 1.22, 1.22, 1.3,</p> <p>20 something, 7. Those five values indicate to me a</p> <p>21 tendency of increasing risk with increasing</p> <p>22 exposure. Whether it is -- whether there's formal</p> <p>23 proof of that in a -- from a statistical</p> <p>24 significance point of view is a secondary issue as</p> <p>25 to compared with whether the data are compatible</p>	<p>1 Q The Draft Screening Assessment, right.</p> <p>2 A Yes.</p> <p>3 Q Okay. And specifically, let me direct</p> <p>4 your attention to Roman number -- Roman numeral</p> <p>5 III of that document.</p> <p>6 A Yes.</p> <p>7 Q Okay.</p> <p>8 MS. BRANSCOME: Michelle, would you mind</p> <p>9 helping me follow along?</p> <p>10 MS. PARFITT: Oh, I'm sure.</p> <p>11 MR. TISI: I can give you my copy.</p> <p>12 MS. PARFITT: Sure. Absolutely.</p> <p>13 MR. KLATT: You may want those.</p> <p>14 MS. BRANSCOME: Thank you. What page</p> <p>15 are we on?</p> <p>16 MS. PARFITT: Counsel, I'm on Roman</p> <p>17 numeral III.</p> <p>18 MS. BRANSCOME: Oh, the page -- I had a</p> <p>19 section number that I couldn't find --</p> <p>20 MS. PARFITT: No. At the bottom it has</p> <p>21 a Roman numeral III.</p> <p>22 BY MS. PARFITT:</p> <p>23 Q Dr. Siemiatycki, referring you to the --</p> <p>24 first, second, third -- fourth full paragraph of</p> <p>25 the Draft Screening Assessment, the fourth full --</p>
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<p>1 with dose-response.</p> <p>2 So as you may recall, in the IARC 2006</p> <p>3 evaluation and in -- I guess in the Langseth</p> <p>4 paper, I think we indicated that we were very</p> <p>5 concerned about the consistency of increased</p> <p>6 risks, but found no evidence of dose-response, and</p> <p>7 that held back any inference that the</p> <p>8 categorization should be greater than a 2B.</p> <p>9 The findings from Terry turn on its head</p> <p>10 the assumptions that were made at IARC that there</p> <p>11 was no evidence of dose-response. Now there is</p> <p>12 evidence of dose-response, whether or not it's</p> <p>13 significant by one test or another test.</p> <p>14 Q All right. Thank you.</p> <p>15 All right. Let me direct your</p> <p>16 attention, if I may, to the Health Canada</p> <p>17 document, specifically the Draft Screening</p> <p>18 Assessment dated December 2018. Again, I believe</p> <p>19 it's in your notebook 4.</p> <p>20 A 6 -- yeah. Yes.</p> <p>21 Q All right.</p> <p>22 A Okay, I have it.</p> <p>23 Q Now -- now --</p> <p>24 A Sorry, the Taher or the Draft Screening</p> <p>25 Assessment?</p>	<p>1 A Begins with "full"?</p> <p>2 Q No, it begins with "The meta-analysis."</p> <p>3 A "The meta-analysis." Yep.</p> <p>4 Q Correct.</p> <p>5 Would you please -- does it state: "The</p> <p>6 meta-analysis of the" -- am I reading this</p> <p>7 correctly?</p> <p>8 "The meta-analysis of the available</p> <p>9 human studies in the peer-reviewed literature</p> <p>10 indicate a consistent and statistically</p> <p>11 significant positive association between perineal</p> <p>12 exposure to talc and ovarian cancer."</p> <p>13 Did I read that correctly?</p> <p>14 A Yes, you did.</p> <p>15 Q All right. Is that your opinion,</p> <p>16 Dr. Siemiatycki, based upon your review of the</p> <p>17 totality of the literature on talc powder --</p> <p>18 talcum powder use and ovarian cancer in the</p> <p>19 genital area?</p> <p>20 A Yes, it is.</p> <p>21 Q All right. It goes on to say: "Further</p> <p>22 available data are indicative of a causal effect."</p> <p>23 Did I read that correctly?</p> <p>24 A Yes, you did.</p> <p>25 Q All right. Is it your opinion based</p>

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<p>Page 302</p> <p>1 upon the totality of not only the epidemiological 2 data and findings but mechanistic data, animal and 3 in vivo data, that indeed the data is indicative 4 of a causal effect? 5 MS. BRANSCOME: Objection. 6 MR. KLATT: Objection. Form. 7 THE WITNESS: I believe it is more 8 likely than not that there is a causal 9 relationship between exposure to talc powder and 10 ovarian cancer. And if those two sentences are 11 taken to be equivalent, then I agree with the 12 sentence. 13 BY MS. PARFITT: 14 Q Well, let me ask you this, 15 Dr. Siemiatycki: You've read the draft 16 assessment, and do you have -- is it fair to say 17 that the methodology that the authors performed 18 throughout the course of this particular draft 19 assessment is the same type of methodology that 20 you have performed for purposes of preparing your 21 report and offering the opinions that you have and 22 will continue to offer the court in -- in the 23 litigation involving talcum powder use and ovarian 24 cancer? 25 MS. BRANSCOME: Objection.</p>	<p>Page 304</p> <p>1 assessment? 2 MS. BRANSCOME: Objection. 3 THE WITNESS: When you say 4 "methodology" -- 5 BY MS. PARFITT: 6 Q Mm-hmm. 7 A -- I'm not sure if you're referring to 8 sort of high level methodology like collecting 9 original data, evaluating it, weighing it, and 10 making inferences on the basis of that data. 11 BY MS. PARFITT: 12 Q What I'm asking is, did the authors 13 perform a Bradford Hill-like causality assessment 14 in the performance of their study entitled Draft 15 Screening Assessment? 16 MR. KLATT: Objection. Form. 17 THE WITNESS: You're saying in the pages 18 between 15 and -- 19 BY MS. PARFITT: 20 Q Correct. I'll shorten it by -- 21 A -- 21? 22 Q Correct. Correct. 23 And if I can refer your attention to or 24 direct you to page 20. 25 A They commented on various considerations</p>
<p>Page 303</p> <p>1 THE WITNESS: The authors of this report 2 I think include a group -- a multidisciplinary 3 group, including toxicologists and possibly 4 environmental scientists. I'm not familiar with 5 them, so I can't say for sure. And in that sense, 6 they cover a broader disciplinary background than 7 I cover myself. So in that sense, they have a 8 broader scope to evaluate the totality of the 9 evidence than I have. 10 Their evaluation of the epidemiologic 11 evidence seems in line with my own, and I have no 12 reason to doubt the validity of their toxicologic 13 analyses of the evidence. 14 BY MS. PARFITT: 15 Q All right. Dr. Siemiatycki, 16 specifically let me refer you to page 15, and it's 17 entitled "Perineal Exposure to Talc." And let me 18 know when you get there. 19 A Yes, I'm there. 20 Q All right. Based upon your review of 21 that section beginning on page 15, and I believe 22 it goes all the way through page 21, are you able 23 to -- do you have a sense as to the methodology 24 again that the authors of the draft assessment 25 employed in order to arrive at their causal</p>	<p>Page 305</p> <p>1 that Bradford Hill mentioned in his article. 2 Q And which ones did they provide 3 information and findings on? 4 A They commented on the strength of the 5 association, on consistency, specificity, 6 temporality, biological gradient, biological 7 plausibility, and coherence. 8 Q And what did the authors conclude -- 9 after looking at the various Bradford Hill 10 factors, what did they conclude in that last 11 paragraph of their Bradford Hill assessment? 12 A "Suggests a small but consistent 13 statistically significant positive association 14 between ovarian cancer and perineal exposure to 15 talc. Further available data are indicative of a 16 causal effect." 17 Is it -- is that what you're referring 18 to? 19 Q Yes. And do you agree with the authors 20 of the draft report of December 2018, when they 21 conclude that: "The most recent meta-analysis 22 detailed, Taher 2018, and consistent with the Hill 23 criteria suggest a small but consistent 24 statistically significant positive association 25 between ovarian cancer and perineal exposure to</p>

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<p>1 talc. Further available data are indicative of a 2 causal effect"? 3 A Yes. 4 MR. KLATT: Objection to form. 5 BY MS. PARFITT: 6 Q Thank you. All right. 7 Let me ask a couple other questions, and 8 I need you -- if you will, can you reach over 9 there, I believe it was exhibit number -- do you 10 see your book on occupational diseases? I think 11 it's under -- there you go. Okay. 12 Okay. Now, you were asked many hours 13 ago some questions regarding the book Risk Factors 14 for Cancer in the Workplace. 15 Do you recall that? 16 A Yes, I do. 17 Q All right. And that is indeed a book 18 that was authored by you, Jack Siemiatycki, 19 correct? 20 A Correct. 21 Q All right. And I believe you were asked 22 whether there was anything in your book that 23 described the methodology that you have employed 24 over the course, and I believe you said the last 25 four decades or almost four decades.</p>	<p>1 you have copies in that binder that you had 2 printed out. 3 MS. BRANSCOME: May I have a copy if he 4 is going to read from it? 5 MS. PARFITT: Absolutely. And I thought 6 we had -- do you have any copies in there? 7 THE WITNESS: Oh, for this -- 8 MS. PARFITT: No. 9 MR. TISI: It wasn't marked. It was in 10 the stuff you printed out. 11 MS. PARFITT: I think I've got one here. 12 (A discussion was held off the record.) 13 MS. PARFITT: Ms. Branscome, here you 14 go. Here's copies. 15 And let's have this marked as now 16 exhibit -- I'm not sure what we're up to. 17 MR. TISI: We're up to 18. 18. 18 MS. PARFITT: 18. Okay. 19 And for the record, we are marking the 20 face sheet of the book Risk Factors for Cancer in 21 the Workplace by Jack Siemiatycki, and 22 specifically the table -- 23 MS. BRENNAN: I have 16. 24 MR. TISI: No, because he marked -- 25 MS. BRENNAN: Yeah, 14 --</p>
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<p>1 Do you recall those questions? 2 A Yes, I do. 3 MS. BRANSCOME: Objection. 4 BY MS. PARFITT: 5 Q All right. Where in that book, if there 6 is something in that book, does it describe the 7 methodology that you have employed over the course 8 of the last four decades that you still employ 9 today in your analysis and opinions and findings 10 in the talcum powder product litigation and 11 ovarian cancer? 12 MS. BRANSCOME: Object to form. 13 THE WITNESS: I'm looking for -- well, I 14 guess the main thing I would -- I would summarize 15 that -- 16 BY MS. PARFITT: 17 Q And could you tell us for the record -- 18 A Yes. 19 Q -- Dr. Siemiatycki, where you are? 20 A Where I'm reading? 21 Q Yes, please. 22 A Thank you. I'm looking at page 298 in 23 this book, and I -- did you provide a copy of that 24 chapter? 25 MR. TISI: Doctor, you have copies --</p>	<p>1 MR. KLATT: Actually, it should be 16. 2 MS. PARFITT: 16? Thank you. 16. 3 All right. We are now marking as 4 Exhibit 16 the book entitled Risk Factors for 5 Cancer in the Workplace by Dr. Jack Siemiatycki, 6 which specifically includes the table of contents, 7 Chapter 7, "Interpretation of Findings," pages 297 8 through 308. 9 MR. DONATH: Is that an excerpt, not the 10 whole thing? 11 MS. PARFITT: It is -- it is not. We'll 12 make the book available, but it's just the 13 excerpt. 14 (Exhibit No. 16 was marked for 15 identification.) 16 MS. BRANSCOME: Did someone just join 17 the line? 18 THE REPORTER: They hung up. 19 THE WITNESS: Shall I read a couple of 20 paragraphs from this? 21 BY MS. PARFITT: 22 Q Well, the question was -- the question 23 was whether or not there was any bases or writings 24 that discussed the methodology that you've 25 employed over the last four decades, and you</p>

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<p>1 commented that it was in your book.</p> <p>2 MS. BRANSCOME: Object --</p> <p>3 BY MS. PARFITT:</p> <p>4 Q So please tell us what's in your book.</p> <p>5 MS. BRANSCOME: Object to form.</p> <p>6 THE WITNESS: Well, I -- I won't read</p> <p>7 the whole book.</p> <p>8 BY MS. PARFITT:</p> <p>9 Q I appreciate that. We all --</p> <p>10 A I have a phone book downstairs that I</p> <p>11 could -- no, I will just read a couple of</p> <p>12 paragraphs that talk about interpreting and</p> <p>13 conducting epidemiologic research in general, not</p> <p>14 specifically related to this particular study --</p> <p>15 set of studies that I describe in the book.</p> <p>16 "The main purpose of epidemiology is to</p> <p>17 find the cause of disease. Despite some</p> <p>18 controversy concerning the validity of drawing</p> <p>19 causal inferences in epidemiology. There is a</p> <p>20 consensus that sanctions and provides guidelines</p> <p>21 for the practice. The evaluation of causality</p> <p>22 between a putative risk factor and disease is a</p> <p>23 complex and subjective process. Equally competent</p> <p>24 scientists examining the same information can</p> <p>25 arrive at different conclusions. However, as</p>	<p>1 Is that what you were --</p> <p>2 Q That's what I wanted to know.</p> <p>3 A -- asking?</p> <p>4 Q Thank you. All right.</p> <p>5 Now, do you recall, Dr. Siemiatycki,</p> <p>6 that you were asked some questions about the</p> <p>7 mechanism underlying exposure to talc and genital</p> <p>8 use of talcum powder products and ovarian cancer?</p> <p>9 Do you remember Ms. Branscome asked you some</p> <p>10 questions about that?</p> <p>11 A The mechanism of exposure or the</p> <p>12 mechanism of carcinogenesis?</p> <p>13 Q The mechanism of exposure --</p> <p>14 A Okay.</p> <p>15 Q -- between talcum powder products and</p> <p>16 ovarian cancer. Do you remember there were a</p> <p>17 series of questions that were asked about that?</p> <p>18 MS. BRANSCOME: Object to form.</p> <p>19 THE WITNESS: I'm -- I'm not --</p> <p>20 BY MS. PARFITT:</p> <p>21 Q Okay. Let me -- okay. Let me -- let me</p> <p>22 do this. Let me refer you to your report, if you</p> <p>23 will, and I believe it's been marked as -- I think</p> <p>24 this is 10 -- as 10.</p> <p>25 Do you have your report in front of you?</p>
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<p>1 additional evidence is accumulated, beliefs and</p> <p>2 consensuses may change. The criteria that are</p> <p>3 most relevant to the problem of evaluating</p> <p>4 causality between cancer and an antecedent</p> <p>5 occupational exposure may be paraphrased as</p> <p>6 follows:</p> <p>7 Number 1: "Is sampling variability a</p> <p>8 plausible explanation for the observed</p> <p>9 association?"</p> <p>10 Number 2: "How strong is the</p> <p>11 association and is there a dose-response</p> <p>12 relationship?"</p> <p>13 Number 3: "Is bias or confounding a</p> <p>14 plausible explanation for the observed</p> <p>15 association?"</p> <p>16 Number 4: "Is the association</p> <p>17 biologically plausible?"</p> <p>18 Number 5: "Is there relevant supporting</p> <p>19 evidence from other epidemiologic studies or from</p> <p>20 non-human test systems, such as animal</p> <p>21 experimentation or tests of mutagenicity?"</p> <p>22 I'll stop there. But in answer to your</p> <p>23 question, this text, published 30 years ago now,</p> <p>24 encapsulates my approach to how to interpret and</p> <p>25 use epidemiologic evidence in assessing causality.</p>	<p>1 A Yes.</p> <p>2 Q Very good. Okay.</p> <p>3 All right. And specifically I'm</p> <p>4 referring to page 64 and 65.</p> <p>5 A So I'm one or two pages off, so just</p> <p>6 tell me which section.</p> <p>7 Q Okay. I believe it's -- it's under</p> <p>8 "Biological Plausibility." Do you see that in the</p> <p>9 lower part? Let's see.</p> <p>10 A "Biological Plausibility" -- (reading to</p> <p>11 himself.) Strength. Okay. I've got it</p> <p>12 somewhere -- consistency. Here.</p> <p>13 Q Okay.</p> <p>14 A "Biological Plausibility," yes.</p> <p>15 Q Now, I specific -- I believe</p> <p>16 specifically the question that you were asked is</p> <p>17 whether or not you will be testifying with regard</p> <p>18 to the mechanism and the biological mechanism for</p> <p>19 causing cancer with genital use of talcum powder</p> <p>20 products. Do you remember that?</p> <p>21 A Yes.</p> <p>22 Q Okay. Now, in the course of your</p> <p>23 analysis and in looking at that issue of</p> <p>24 biological mechanism for causing cancer, what did</p> <p>25 you consult and review and assess for purposes of</p>

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<p style="text-align: right;">Page 314</p> <p>1 formulating your opinions on that topic? 2 MS. BRANSCOME: Objection. 3 THE WITNESS: I actually started with 4 the IARC 2006 report where there was a high level 5 subgroup of toxicologists and basic scientists who 6 reviewed the evidence. So I read that material. 7 I've read various articles concerning 8 migration of particles, articles about 9 inflammation as a carcinogenic process, oxidative 10 stress as part of the carcinogenic process. And 11 towards the end, started looking at articles about 12 asbestos in talc as filling in some of the 13 information about what the content of talcum 14 powder products were. I at one point was looking 15 at company documents to try to figure out what 16 were the time relationships of using talc versus 17 using substitutes for talc. So all of those kinds 18 of things I was looking for. 19 BY MS. PARFITT: 20 Q So for purposes of evaluating the 21 evidence and opining on the issue of talcum powder 22 products and ovarian cancer, did you consider the 23 issue of biological plausibility? 24 MS. BRANSCOME: Objection. 25 THE WITNESS: Yes, I considered it.</p>	<p style="text-align: right;">Page 316</p> <p>1 causality. 2 So the bar for establishing plausibility 3 for me is, are there credible scientists who are 4 persuaded or have reasonable confidence that there 5 is a mechanism that can explain the observation. 6 And if so, I would defer to that point of view as 7 being plausible. 8 I would not accept that one or more 9 scientists developing a mechanistic theory are 10 definitely proven, but if there is a credible 11 point of view in the scientific community about 12 the mechanism, I would call that plausible. It 13 doesn't mean it's proven. It's plausible. 14 And to my satisfaction, when I looked at 15 the different reports, including reports of 16 experts in the litigations, I was reasonably 17 assured that there are plausible theories and 18 plausible hypotheses. 19 Q All right. In your section of your 20 expert report on page 64 through 66, did the 21 factors you identify under the subtitle 22 "Biological Plausibility" provide support for your 23 opinions that indeed there is biological 24 plausibility between the use of genital use of 25 talcum powder products and ovarian cancer?</p>
<p style="text-align: right;">Page 315</p> <p>1 BY MS. PARFITT: 2 Q All right. And what was the basis of 3 your opinion as to whether or not there was 4 biological plausibility between talcum powder 5 product use in the genital area and ovarian 6 cancer? 7 MS. BRANSCOME: Objection. Assumes he 8 formed an opinion. 9 THE WITNESS: Well, my -- 10 BY MS. PARFITT: 11 Q Dr. Siemiatycki, did you formulate an 12 opinion with regard to whether there was 13 biological plausibility between the use of talcum 14 powder products and ovarian cancer? 15 A Yes, I did. 16 Q Okay. 17 A And the first part of the discussion is 18 what one means by "plausibility." And so one 19 issue that I took off the table quite soon is the 20 notion that biological plausibility is synonymous 21 with biological proof. Neither Bradford Hill nor 22 anyone else who has described the use of 23 biological plausibility as a criterion has ever 24 claimed that biological proof of a mechanism is 25 necessary before you can opine about the -- about</p>	<p style="text-align: right;">Page 317</p> <p>1 A I think they provide evidence of 2 plausibility for those theories. 3 Q And did you consider those for purposes 4 of opining that talcum powder products in the 5 genital area, used, can cause ovarian cancer? 6 A Yes, I considered them. 7 Q All right. Dr. Siemiatycki, I'm not 8 sure of the -- I don't think we marked it as an 9 exhibit, so let me do that now. I believe we're 10 up to 17. 11 (A discussion was held off the record.) 12 (Exhibit No. 17 was marked for 13 identification.) 14 BY MS. PARFITT: 15 Q All right. Dr. Siemiatycki, do you 16 recall the discussion you had with Ms. Branscome, 17 again several hours ago, on the issue of 18 confounding and how that can impact study designs? 19 A Oh, yes. 20 Q All right. Let me show you a document 21 we have marked as Exhibit No. 17, and it's 22 entitled "Degree of confounding bias related to 23 smoking ethnic group, and socioeconomic status and 24 estimates of the association between occupation 25 and cancer," and I believe that's an article that</p>

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<p>1 you were an author, correct?</p> <p>2 A That's correct, yes.</p> <p>3 Q All right. What, if any, support did</p> <p>4 that particular article that you wrote, I guess</p> <p>5 back in 1988, provide, if any, for the opinions</p> <p>6 that you've rendered in this case on the topic of</p> <p>7 confounding and bias?</p> <p>8 A In this study we evaluated 75</p> <p>9 associations, 25 occupations in relation to lung</p> <p>10 cancer, to bladder cancer and to stomach cancer,</p> <p>11 each of them. And we looked at the association</p> <p>12 between each occupation and each of the three</p> <p>13 types of cancer, adjusting for the smoking history</p> <p>14 of the patients and the subjects. But another set</p> <p>15 of analyses not adjusting for their smoking</p> <p>16 histories, and their socioeconomic status and</p> <p>17 their ethnic group. These are factors that are</p> <p>18 strongly associated with cancer and with different</p> <p>19 occupations. We wanted to see how large a</p> <p>20 confounding bias could be generated by not having</p> <p>21 proper confounder information.</p> <p>22 And so I will just read a couple of</p> <p>23 sentences from the abstract of this article.</p> <p>24 "Of the 75 associations studied, only</p> <p>25 one OR was distorted by more than 40 percent. A</p>	<p>1 low probability.</p> <p>2 And this is part of what leads me and</p> <p>3 what led me in my report to opine that confounding</p> <p>4 is unlikely to be the explanation for the observed</p> <p>5 relative risks.</p> <p>6 Q Thank you. All right.</p> <p>7 THE VIDEOGRAPHER: Excuse me, Counsel.</p> <p>8 MS. PARFITT: Off the record, yes.</p> <p>9 THE VIDEOGRAPHER: Off the record?</p> <p>10 MS. PARFITT: Yeah, it's a good time,</p> <p>11 because you're running out of tape. I could tell.</p> <p>12 THE VIDEOGRAPHER: Going off the record</p> <p>13 at 8:27 p.m.</p> <p>14 (Recess.)</p> <p>15 THE VIDEOGRAPHER: We're going back on</p> <p>16 the record at 8:31 p.m.</p> <p>17 MS. PARFITT: Thank you.</p> <p>18 BY MS. PARFITT:</p> <p>19 Q Dr. Siemiatycki, just one last question.</p> <p>20 Let me direct your attention to again</p> <p>21 the documents in your Exhibit No. 4, specifically</p> <p>22 the "Weight of Evidence: General Principles and</p> <p>23 Current Applications at Health Canada," which</p> <p>24 formed part of the Health Canada recommendation.</p> <p>25 All right?</p>
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<p>1 40 percent distortion would correspond to an odds</p> <p>2 ratio of 1.4 when comparing unadjusted with</p> <p>3 adjusted estimates. Three were distorted by</p> <p>4 between 30 percent and 40 percent, and four others</p> <p>5 by between 20 percent and 30 percent."</p> <p>6 So of these 75 associations, not taking</p> <p>7 account of very powerful confounders -- smoking is</p> <p>8 the most powerful confounder we know. Ethnicity</p> <p>9 and socioeconomic status are important</p> <p>10 confounders. They have strong relative risks with</p> <p>11 these different cancers. Not taking them into</p> <p>12 account could create artifactual odds ratios,</p> <p>13 maximum of 1.4, even though the original odds</p> <p>14 ratios of the confounders with these cancers could</p> <p>15 be as high as 10.</p> <p>16 So there's a very -- the confounding</p> <p>17 effect, at most, would be 10 percent or 20</p> <p>18 percent, but the likelihood that there is some</p> <p>19 unknown confounder with -- with ovarian cancer</p> <p>20 that is artifactually creating across the board,</p> <p>21 across all these studies, an artifactual relative</p> <p>22 risk of around 1.3 would require some -- that</p> <p>23 unknown confounder to have an extremely high</p> <p>24 relative risk, certainly higher than 2, maybe</p> <p>25 higher than 3 or 4, which is not inconceivable but</p>	<p>1 A I'm not sure if it formed part of the</p> <p>2 recommendation or if it's a background document.</p> <p>3 Q Very good. I think you're probably</p> <p>4 right.</p> <p>5 All right. And you have -- you have had</p> <p>6 a chance to review that, correct?</p> <p>7 A Yes.</p> <p>8 Q All right. Specifically let me direct</p> <p>9 your attention to page 7 of that document. And</p> <p>10 I'm going to go down to the very last paragraph,</p> <p>11 and it starts with: "The majority of risk</p> <p>12 assessment reports, however, provide a logical</p> <p>13 narrative description of the relative strengths or</p> <p>14 weakness of various lines of evidence considered.</p> <p>15 For most risk assessments, individual lines of</p> <p>16 evidence are polled and integrated into a final</p> <p>17 conclusion based on best professional judgment and</p> <p>18 not mathematical formula."</p> <p>19 Did I read that correctly?</p> <p>20 A Yes, you did.</p> <p>21 Q Do you agree with the statement by</p> <p>22 Health Canada in their "Weight of Evidence:</p> <p>23 General Principles"?</p> <p>24 A Yes, I do.</p> <p>25 MS. PARFITT: All right. I have no</p>

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<p>1 further questions. Thank you.</p> <p>2 THE WITNESS: This is also in conformity</p> <p>3 with all guidelines from agencies and experts who</p> <p>4 understand science.</p> <p>5 MS. PARFITT: Very good.</p> <p>6 THE WITNESS: The best data is</p> <p>7 collected, compiled, and then interpreted by human</p> <p>8 expert judgment.</p> <p>9 MS. PARFITT: Thank you very much,</p> <p>10 Dr. Siemiatycki. I believe counsel has some</p> <p>11 follow-up.</p> <p>12 MS. BRANSCOME: I do, but I think I need</p> <p>13 to take a break to confer amongst ourselves.</p> <p>14 MS. PARFITT: Go ahead.</p> <p>15 THE VIDEOGRAPHER: We're going off the</p> <p>16 record at 8:33 p.m.</p> <p>17 (Recess.)</p> <p>18 THE VIDEOGRAPHER: We are going back on</p> <p>19 the record at 8:46 p.m.</p> <p>20 REDIRECT EXAMINATION</p> <p>21 BY MS. BRANSCOME:</p> <p>22 Q Good evening, Dr. Siemiatycki.</p> <p>23 I have some follow-up questions to the</p> <p>24 questions that were just asked to you by</p> <p>25 plaintiffs' counsel.</p>	<p>1 gist of it was whether the paper has been or will</p> <p>2 be submitted for publication. I don't recall if</p> <p>3 there were other important components. It was a</p> <p>4 brief message, besides pleasantries of people</p> <p>5 who've known each other for 30 years.</p> <p>6 But, you know, I said I -- I've learned</p> <p>7 about this work that you were involved with. I</p> <p>8 can't remember what else I said.</p> <p>9 Q In your e-mail communication to</p> <p>10 Dr. Krewski, did you alert him to the fact that</p> <p>11 you were serving as a -- an expert on behalf of</p> <p>12 plaintiffs' counsel in litigation involving talcum</p> <p>13 powder?</p> <p>14 A I don't recall. Your question used the</p> <p>15 plural, and in my -- you said "in your</p> <p>16 communications." That's what I heard. No? Okay.</p> <p>17 Q I meant it in the singular.</p> <p>18 A You meant it in the singular, so I guess</p> <p>19 the record will reflect.</p> <p>20 In my one message to Dr. Krewski -- let</p> <p>21 me -- if I may.</p> <p>22 Q My question again, Dr. Siemiatycki --</p> <p>23 A Yeah, please.</p> <p>24 Q -- is in your e-mail to Dr. Krewski with</p> <p>25 respect to the Taher paper, did you notify him in</p>
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<p>1 Both myself and counsel for Imerys asked</p> <p>2 you very specifically if you had had contact with</p> <p>3 any of the authors in connection with the Taher</p> <p>4 paper or the Health Canada paper. Do you recall</p> <p>5 the questions that we asked you?</p> <p>6 A I -- I recall that you asked questions</p> <p>7 about it, yes.</p> <p>8 Q Yeah. Is there a reason why during my</p> <p>9 questioning and questioning by counsel for Imerys</p> <p>10 you did not recall having sent an e-mail to</p> <p>11 Dr. Krewski with respect to the potential</p> <p>12 publication of the Taher paper?</p> <p>13 A I -- I guess I consider -- well, two</p> <p>14 parts. I consider a contact sort of a two-way</p> <p>15 process, and there was no two-way process. I sent</p> <p>16 him a message. He never responded.</p> <p>17 And number two, it -- it dropped off of</p> <p>18 my memory screen. I -- I just forgot about it</p> <p>19 until she asked.</p> <p>20 Q When did you contact Dr. Krewski about</p> <p>21 the Taher paper?</p> <p>22 A In December, when I first learned about</p> <p>23 it.</p> <p>24 Q What specifically did you ask him?</p> <p>25 A My recollection, I asked him if -- the</p>	<p>1 that e-mail that you were serving as an expert</p> <p>2 witness retained on behalf of plaintiffs' counsel</p> <p>3 in litigation involving talcum powder?</p> <p>4 A I -- I -- I don't recall if I did or</p> <p>5 not. I -- I wouldn't have thought it was a</p> <p>6 crucial thing to indicate in this first message</p> <p>7 asking him if his paper was in press or in</p> <p>8 publication or something like that.</p> <p>9 Q Why did you want to know whether it had</p> <p>10 been submitted for publication?</p> <p>11 A I wanted to know what the status of that</p> <p>12 report was. I had no -- I didn't follow up my --</p> <p>13 it wasn't an important issue for me. I was -- it</p> <p>14 was kind of an idle gesture of, you know, Hi, I</p> <p>15 haven't heard from you for a while. I see that</p> <p>16 you have this thing. Are you sending it for</p> <p>17 publication? Something like that.</p> <p>18 And I -- the motivation, was there a</p> <p>19 specific ulterior motive? No, there was no --</p> <p>20 there was nothing I would have done differently.</p> <p>21 I guess if he had told me, yes, it's about to be</p> <p>22 submitted, I would have wanted to see the final</p> <p>23 version, because the version that I saw was</p> <p>24 obviously an early manuscript. It was much too</p> <p>25 long for a -- for a publication submission. But</p>

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<p>1 it wasn't a big deal for me to -- to have 2 information about that manuscript. 3 Q Including communications in which you 4 unilaterally reached out to individuals but may 5 not have received a response, have you 6 communicated in any form with any of the 7 participants in the development of the Health 8 Canada Draft Screening Assessment or the Taher 9 paper, other than what we have discussed with 10 respect to Dr. Krewski? 11 A No. 12 Q The Health Canada Draft Screening 13 Assessment, you were asked a number of questions 14 about that by counsel for plaintiffs. Is that a 15 document that you have reviewed closely in forming 16 your opinions in this case? 17 MS. PARFITT: Objection. Form. 18 THE WITNESS: I wouldn't say that I 19 reviewed it closely the way I've reviewed the 20 evidence before submitting my report. No. 21 BY MS. BRANSCOME: 22 Q All right. I want to talk to you about 23 Exhibit 17. You have that over there. It's the 24 "Degree of confounding bias related to smoking." 25 A Oh, yeah.</p>	<p>1 Did I read that correctly? 2 MS. PARFITT: Counsel, just with one 3 correction. It came out as "estimates." The 4 article says "estimates," and it came out on the 5 transcript as "assessments." 6 MS. BRANSCOME: Okay. 7 THE WITNESS: That -- do you understand 8 what she's indicated? 9 BY MS. BRANSCOME: 10 Q Yes. Did I read it correctly? 11 A You misread one word. 12 Q Okay. 13 A But it's not important, but if you want 14 to have it for the record. 15 Q Well, we can continue on. 16 A Yes. 17 Q "This consideration follows from the 18 recognition that some degree of bias is quite 19 likely in any non-experimental study." 20 Did I read that correctly? 21 A Yes. 22 Q "Small excess relative risks, even if 23 they are statistically significant, are often 24 interpreted with great caution, if not 25 skepticism."</p>
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<p>1 Q All right. Dr. Siemiatycki, is 2 Exhibit 17 an article that you identified to 3 address the likelihood that a confounding variable 4 could explain the increased risk that you have 5 found in your meta-analysis with respect to the 6 use of talc? 7 A Yes. 8 Q Okay. So I just want to direct you to 9 page 623. In the right-hand column, do you see a 10 paragraph that begins "One of the criteria"? 11 A Yes. 12 Q Does it state: "One of the criteria 13 used by epidemiologists to distinguish true from 14 false associations is the strength of the 15 association"? Did I read that correctly? 16 A Yes, you did. 17 Q And again, this is an article on which 18 you are the lead author, correct? 19 A Correct. 20 Q It continues on: "That is, among two 21 relative risk assessments which have equal levels 22 of statistical significance but one of which is 23 much greater than 1, while the other is closer 24 to 1, the larger one is considered more likely to 25 reflect a true association than the smaller one."</p>	<p>1 Did I read that correctly? 2 A Yes. 3 Q "Although there has been no explicit 4 consensus on what level of excess relative risk 5 should be considered too small to be taken 6 seriously, we believe that many epidemiologists 7 use a cut point in the range of 1.2 to 1.5 for 8 this purpose. Our results indicate that a cut 9 point in this range is reasonable for studies of 10 cancer occupation associations." 11 Did I read that correctly? 12 A Yes, you did. 13 Q And the references in those sentences to 14 the words "we" and "our" would include you, 15 Dr. Siemiatycki, correct? 16 A Correct. 17 Q And then if we could turn the page to 18 page 624, the paragraph at the top on the 19 left-hand column, I direct your attention to the 20 last complete sentence of that paragraph. 21 "On the other hand, our results also 22 imply that relative risk estimates as low as 1.2 23 for lung cancer associations or 1.1 for bladder or 24 stomach cancer associations run a fair chance of 25 being attributable to confounding bias, even if</p>

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<p>1 they are," quote, "statistically significant." 2 Did I read that correctly? 3 A Yes, you did. 4 Q Is that a conclusion that you and your 5 authors reached in the paper that's been 6 identified as Exhibit 17? 7 A Yes, it was. 8 Q Your opinion with respect to the 9 existence of biological plausibility of the 10 perineal use of talc and ovarian cancer is limited 11 to the evaluation of whether or not there are 12 credible scientists who are persuaded that there 13 is a mechanism; is that correct? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: Can you repeat that? I'm 16 sorry. 17 BY MS. BRANSCOME: 18 Q Your opinion with respect to the 19 existence of biological plausibility of the 20 perineal use of talc and its potential to cause 21 ovarian cancer is limited to an evaluation of 22 whether or not there are credible scientists who 23 are persuaded that there is a mechanism, correct? 24 MS. PARFITT: Objection. Form. 25 Misstates his testimony.</p>	<p>1 MS. PARFITT: Object to form. 2 THE WITNESS: Correct. 3 BY MS. BRANSCOME: 4 Q You indicated in response to questions 5 by plaintiffs' counsel that you were persuaded by 6 the opinions of other experts in the litigation 7 with respect to biological plausibility. Who are 8 those experts? 9 A I -- I think I indicated that such 10 experts contributed to the information that I had, 11 not that they were the only ones who persuaded me. 12 So there was literature and there were depositions 13 and reports. 14 So -- I'm trying to remember the names 15 of the various expert reports that I have read and 16 depositions. I do -- there's the Plunkett, the 17 Saed papers, but I don't know if there was a 18 report by Saed. There was -- let me look in my 19 list of references. (Peruses document.) 20 I'm sorry, I'm drawing a blank on the 21 names of the people whose reports and testimonies 22 I've read in the last month or two. 23 Q When were you provided with copies of 24 these expert reports? 25 A In the fall. Some before November 15th</p>
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<p>1 THE WITNESS: I would say is based on, 2 rather than is limited to. 3 BY MS. BRANSCOME: 4 Q Do you have expertise that would allow 5 you to determine what the most likely biological 6 mechanism is, if there is one, for perineal use of 7 talc to cause ovarian cancer? 8 A No, I wouldn't pretend to -- to have 9 that kind of expertise. 10 Q Okay. Is it also true that you are not 11 qualified to opine on the ability or not of talc 12 particles to migrate to the ovaries from the use, 13 the perineal application of talc? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: Not on the basis of my 16 research, not on the basis of my training, but on 17 the basis of my reading of literature concerning 18 that issue, I have an opinion based on what I've 19 read from experts in the -- that field. 20 BY MS. BRANSCOME: 21 Q But in forming that opinion, you are 22 relying on -- 23 A Yes. 24 Q -- the expertise of others, correct? 25 A Yes.</p>	<p>1 and some after November 15th. And -- but also 2 I'm -- I'm reflecting on the various reports and 3 testimonies from the earlier trial, and I read 4 various expert reports from that time. 5 Q Did you draft the section in your MDL 6 expert report related to biologic plausibility? 7 A Yes, I did. 8 Q You personally summarized each of the 9 various studies that you refer to in that section? 10 A What do you mean by summarized the 11 studies? I -- I summarized the evidence that's 12 captured there, and I provided references for 13 those statements, yes. 14 Q You're the original author of the 15 language in that section is my question. 16 A Yes. Yes. 17 Q Can you identify for me which expert 18 reports related to biological plausibility you had 19 reviewed before forming your opinion as 20 represented in the MDL report? 21 A As I said, it's partly a number of 22 reports that I had seen in the previous trial, and 23 I -- I'm drawing a blank on the names of -- of the 24 people. 25 Q You understand that there will be</p>

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<p>1 experts retained by defense counsel who will 2 provide reports addressing biological 3 plausibility, correct? 4 A I assume so, yeah. 5 Q Okay. Are you qualified to evaluate 6 between competing expert reports who is correct 7 about the biological mechanism? 8 MS. PARFITT: Objection. Form. 9 BY MS. BRANSCOME: 10 Q To the extent one exists. 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: No -- no, I wouldn't be. 13 I mean I -- I can read reports from people outside 14 my area and form an opinion about the general 15 coherence and -- and form an initial sense of the 16 credibility of the various reports. And I'd be 17 happy to review the reports of the experts for the 18 defense on these issues. 19 BY MS. BRANSCOME: 20 Q But to the extent, for example, that 21 there are credible experts on both sides of the 22 debate, whether or not there has been an 23 established biological mechanism and whether or 24 not there have not been, you are not qualified to 25 evaluate between the two credible experts?</p>	<p>1 THE VIDEOGRAPHER: We are going off the 2 record at 9:05 p.m. 3 (Pause in the proceedings.) 4 THE VIDEOGRAPHER: We're back on the 5 record at 9:06 p.m. 6 MS. BRANSCOME: At this time I will pass 7 questioning to counsel for Imerys. 8 MS. PARFITT: Thank you. 9 REDIRECT EXAMINATION 10 BY MR. KLATT: 11 Q Dr. Siemiatycki, a few more questions, 12 sir. 13 I'm going to read a statement and ask if 14 you agree with it. Okay? 15 A Yes. 16 Q "When a pronounced binary association is 17 present, use of the never or no category in 18 assessing trend can induce a trend where none 19 exists." 20 A Okay. Can you -- yeah, thank you. 21 Q And my question is, do you agree or 22 disagree with that statement? 23 A Yes, I agree it can -- I agree with it. 24 There are some qualifiers that I would add to that 25 sentence, but I agree with it.</p>
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<p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: That's correct. And I've 3 never pretended that -- make -- that it is 4 necessary for me to establish the correct 5 biological mechanism before drawing inferences 6 about causality. 7 BY MS. BRANSCOME: 8 Q It is your conclusion that more likely 9 than not perineal use of talc can cause ovarian 10 cancer is based on the epidemiological evidence, 11 correct? 12 MS. PARFITT: Objection. Misstates his 13 evidence and testimony today. 14 THE WITNESS: In part -- in large part. 15 Yes. 16 BY MS. BRANSCOME: 17 Q Okay. Well, my question now is about 18 the, in small part, the evidence in addition to 19 that. What evidence are you considering that you 20 are qualified to independently evaluate? 21 A I am qualified to evaluate whether there 22 is a plausible theory about it. Not to establish 23 whether that theory is correct or not. 24 MS. BRANSCOME: Okay. All right. If we 25 could just go off the record very briefly.</p>	<p>1 Q Could you look at your report, please, 2 sir, in the case on page 65, the discussion of 3 biologic plausibility. 4 A Yes. 5 Q And actually I think your biologic 6 plausibility discussion actually begins near the 7 bottom of the previous page, 64, and there's a 8 general discussion on the rest of 64 and the first 9 paragraph or two of 65. Is that correct? 10 A I -- I believe it's correct. The 11 version I have in front of me is that version that 12 has a slightly different formatting, so -- but I'm 13 with you. 14 Q Okay. 15 MS. PARFITT: And I believe, just for 16 completeness, it starts on 60 -- 17 THE WITNESS: Mine starts on -- 18 MS. PARFITT: His document starts on 65, 19 goes all the way over to 66. Mike, yours probably 20 starts on the bottom of 64, goes all the way over 21 to the top of 66. 22 BY MR. KLATT: 23 Q And what I'm focusing on is the 24 paragraph that you wrote that begins with 25 "Insofar" --</p>

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<p>1 A Yes.</p> <p>2 Q -- which is where your specific</p> <p>3 discussion of biologic plausibility regarding</p> <p>4 talcum powder products begins.</p> <p>5 A Yes.</p> <p>6 Q Do you -- do you see that paragraph,</p> <p>7 sir?</p> <p>8 A Yes, I do.</p> <p>9 Q And moving down, did you read the</p> <p>10 articles that you cited here carefully?</p> <p>11 A I read them. I'm not capable of fully</p> <p>12 understanding articles in areas that are outside</p> <p>13 my area of -- of expertise. But to the --</p> <p>14 Q Well --</p> <p>15 MS. PARFITT: Wait, let him finish.</p> <p>16 THE WITNESS: To the extent that I was</p> <p>17 able to understand them, I read these articles.</p> <p>18 BY MR. KLATT:</p> <p>19 Q I'm focusing on the sentence that you</p> <p>20 wrote in your report saying: "First of all, there</p> <p>21 are two possible routes that talcum powder</p> <p>22 products can take to reach the ovaries."</p> <p>23 Do you see where I am?</p> <p>24 A Yes, I do.</p> <p>25 Q The next sentence says: "There is</p>	<p>1 A I think so. Is this --</p> <p>2 Q And the --</p> <p>3 A Is this the South African study?</p> <p>4 Q I believe you're right.</p> <p>5 A Okay.</p> <p>6 Q And the women were not women using</p> <p>7 perineal talc. They were women who were being</p> <p>8 prepared to undergo gynecologic surgery, correct?</p> <p>9 A Correct.</p> <p>10 Q And after this solution of albumin</p> <p>11 microspheres was injected at the top of the</p> <p>12 vaginal vault, the women were tilted in a head</p> <p>13 down/pelvis up position for two hours beforehand,</p> <p>14 correct?</p> <p>15 A Correct.</p> <p>16 Q So --</p> <p>17 A Now I'm saying correct, but I don't</p> <p>18 remember the details that you're quoting. I</p> <p>19 remember the article. I'm -- I -- it doesn't --</p> <p>20 my recollection doesn't contradict anything you're</p> <p>21 saying.</p> <p>22 Q So Venter doesn't tell us anything at</p> <p>23 all about dry talc particles applied externally to</p> <p>24 the genital area being able to migrate up the</p> <p>25 vagina, across the cervix, up the uterus, up the</p>
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<p>1 published evidence that talcum powder products and</p> <p>2 its constituents and contaminants that are applied</p> <p>3 to the vaginal area can migrate from there to the</p> <p>4 fallopian tubes and ovaries," citing Venter 1979,</p> <p>5 Henderson 1986, Heller 1996, "or to pelvic lymph</p> <p>6 nodes," citing Cramer 2007.</p> <p>7 Is that correct?</p> <p>8 A Yes, that's correct.</p> <p>9 Q Do you recall, Dr. Siemiatycki, that the</p> <p>10 Venter 1979 article has nothing to do with talc at</p> <p>11 all?</p> <p>12 MS. PARFITT: Objection. Form.</p> <p>13 THE WITNESS: Is that the article about</p> <p>14 asbestos?</p> <p>15 BY MR. KLATT:</p> <p>16 Q Venter 1979 is the article about albumin</p> <p>17 microspheres.</p> <p>18 A Oh, yeah. Yes.</p> <p>19 Q Do you recall that article?</p> <p>20 A I do. Well, I don't recall it well, but</p> <p>21 I recall reading it a year or two ago.</p> <p>22 Q And in Venter, nothing was applied to</p> <p>23 the perineal area, correct? These albumin</p> <p>24 microspheres were actually injected at the top of</p> <p>25 the vaginal vault, correct?</p>	<p>1 fallopian tubes to the ovaries, correct?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: I guess I use this as a</p> <p>4 reference because some other experts used it as a</p> <p>5 reference for such a statement. And I read the</p> <p>6 article, and it sounded plausible.</p> <p>7 BY MR. KLATT:</p> <p>8 Q But you'd agree with me that the Venter</p> <p>9 1979 article doesn't involve talc particles,</p> <p>10 doesn't involve external application, and is a</p> <p>11 very artificial situation compared to the</p> <p>12 situation of women applying talc to the --</p> <p>13 MS. PARFITT: Objection.</p> <p>14 BY MR. KLATT:</p> <p>15 Q -- external genital area?</p> <p>16 MS. PARFITT: I'm sorry, Michael.</p> <p>17 Objection. Form.</p> <p>18 THE WITNESS: I -- I -- I don't disagree</p> <p>19 with what you said.</p> <p>20 BY MR. KLATT:</p> <p>21 Q And then the other two articles you</p> <p>22 cite, Henderson 1986 and Heller 1996, say nothing</p> <p>23 at all about migration of talc particles. They</p> <p>24 simply observe talc particles in tissue already</p> <p>25 without any reference to how they got there,</p>

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<p>1 correct?</p> <p>2 MS. PARFITT: Do you need to see the</p> <p>3 articles?</p> <p>4 THE WITNESS: Yes, I think I need to see</p> <p>5 those articles.</p> <p>6 MS. PARFITT: Do we have Henderson or</p> <p>7 Heller?</p> <p>8 MR. KLATT: I'm sorry, I don't have them</p> <p>9 with me.</p> <p>10 MS. PARFITT: Okay. Let's see. In your</p> <p>11 report -- they're in your report.</p> <p>12 BY MR. KLATT:</p> <p>13 Q And you might want to pull Cramer 2007</p> <p>14 while you're at it, because again my question is</p> <p>15 the same, it doesn't say anything at all about</p> <p>16 migration. It simply identifies particles already</p> <p>17 in tissue without saying how they got there.</p> <p>18 MS. PARFITT: Okay. Well, let's wait</p> <p>19 for a question and let's get the articles. Let's</p> <p>20 see. It would be tab -- it's a big binder.</p> <p>21 BY MR. KLATT:</p> <p>22 Q Can I -- can I --</p> <p>23 THE WITNESS: I have it in my office.</p> <p>24 BY MR. KLATT:</p> <p>25 Q Can I short-circuit this?</p>	<p>1 MS. PARFITT: Objection. Form.</p> <p>2 Make sure you've read the article.</p> <p>3 THE WITNESS: (Peruses document.) So</p> <p>4 I -- I've skimmed it quickly. I haven't read</p> <p>5 everything, but I don't see that it -- sorry, are</p> <p>6 we on?</p> <p>7 MS. PARFITT: Yes.</p> <p>8 THE VIDEOGRAPHER: We're on the record.</p> <p>9 THE WITNESS: I don't see that it</p> <p>10 directly addresses talc moving from the vagina</p> <p>11 into pelvic lymph nodes, but it certainly concerns</p> <p>12 the detection of talc in pelvic lymph nodes.</p> <p>13 BY MR. KLATT:</p> <p>14 Q But it says nothing in the article</p> <p>15 itself about establishing migration, correct?</p> <p>16 MS. PARFITT: Objection. Misstates his</p> <p>17 testimony.</p> <p>18 BY MR. KLATT:</p> <p>19 Q That you -- that you see.</p> <p>20 MS. PARFITT: Objection. Form,</p> <p>21 misstates his testimony.</p> <p>22 THE WITNESS: I -- I guess, you know --</p> <p>23 the question I would have is if it gets to the</p> <p>24 pelvic lymph nodes, it has to migrate there from</p> <p>25 somewhere. It's not deposited there deliberately.</p>
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<p>1 A Yes.</p> <p>2 Q I think this -- I can short-circuit</p> <p>3 this. If you just look at Cramer 2007. Do you</p> <p>4 have that handy?</p> <p>5 MS. PARFITT: Cramer 2007. Do you have</p> <p>6 it? I don't, Michael.</p> <p>7 THE WITNESS: It would be in my office.</p> <p>8 MR. KLATT: Could we go off for a second</p> <p>9 while you are looking?</p> <p>10 THE VIDEOGRAPHER: We're going off the</p> <p>11 record at 9:15 p.m.</p> <p>12 (Pause in the proceedings.)</p> <p>13 THE VIDEOGRAPHER: We are back on the</p> <p>14 record at 9:17 p.m.</p> <p>15 BY MR. KLATT:</p> <p>16 Q So, Dr. Siemiatycki, at my request,</p> <p>17 you've pulled the 2007 article, first author</p> <p>18 Cramer, called "Presence of talc in pelvic lymph</p> <p>19 nodes of a woman with ovarian cancer and long-term</p> <p>20 genital exposure to cosmetic talc," correct?</p> <p>21 A That's correct.</p> <p>22 Q And my question was simply, this -- this</p> <p>23 article says nothing about talc migrating. It</p> <p>24 simply observes that talc was found in a lymph</p> <p>25 node. Is that correct?</p>	<p>1 BY MR. KLATT:</p> <p>2 Q Well --</p> <p>3 A That was my interpretation of -- of</p> <p>4 this.</p> <p>5 Q Well, look at the very first page of</p> <p>6 this article, Cramer. You see at the very top</p> <p>7 under where the authors are listed?</p> <p>8 A Yes, I do.</p> <p>9 Q It says "Background"?</p> <p>10 A Yeah.</p> <p>11 Q "Although epidemiologic studies suggest</p> <p>12 talc use may increase ovarian cancer risk, there</p> <p>13 is no proof that talc used externally reaches the</p> <p>14 pelvis." Correct?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 BY MR. KLATT:</p> <p>17 Q That's what it says.</p> <p>18 A That's the background to this study.</p> <p>19 That's not --</p> <p>20 Q And it's 2007, correct?</p> <p>21 A Correct.</p> <p>22 Q Which is after the Henderson study that</p> <p>23 you cite. Correct?</p> <p>24 A Correct.</p> <p>25 Q And so after -- and what -- so we have</p>

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<p>1 Venter that you cited and Henderson, and what 2 else? 3 A Heller -- Heller? 4 Q What was the third? Heller, yes. Thank 5 you. 1995. And here is -- 6 MS. PARFITT: No, excuse me. 1996, I 7 believe. 8 BY MR. KLATT: 9 Q Excuse me, 1996. 10 And here in 2007, we have Dr. Cramer 11 saying that there's no proof that externally 12 applied talc reaches the ovaries, correct? 13 MS. PARFITT: Objection. Misstates the 14 science and the article and his testimony. Form. 15 BY MR. KLATT: 16 Q I'm just asking what the article -- what 17 Dr. Cramer and Dr. Godleski said in the Background 18 section to this article that you cite in 2007. 19 MS. PARFITT: Objection. Form. 20 THE WITNESS: You want me to comment on 21 whether their background -- the Background section 22 of this abstract contradicts the thesis that there 23 was evidence of migration before 2007? Is that 24 correct? 25 BY MR. KLATT:</p>	<p>1 proof. They haven't -- they didn't say there is 2 no evidence. They said, There is no proof. 3 BY MR. KLATT: 4 Q Do you understand -- my question, 5 Dr. Siemiatycki, was simply, did Dr. Cramer say 6 there was no proof? Correct? 7 MS. PARFITT: Objection. 8 THE WITNESS: He said there was no 9 proof. 10 MS. PARFITT: Asked and answered. 11 THE WITNESS: He didn't say there was no 12 evidence. 13 BY MR. KLATT: 14 Q Okay. Can you go back -- let's see, 15 let's go back to your expert report on biologic 16 plausibility. 17 MS. PARFITT: Right here. 18 BY MR. KLATT: 19 Q Oh, one other thing. When you were just 20 scanning Cramer 2007, I saw you were looking on 21 the page where he discussed the Heller paper. Did 22 you see that? 23 MS. PARFITT: Just give him a moment to 24 get that again. I think it was 17. 25 THE WITNESS: Sorry. No. 17?</p>
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<p>1 Q I'm -- my question is, you cited Venter 2 and Henderson and Heller for evidence of 3 migration, correct? 4 A Right. Right. 5 Q And those all predate well before 2007, 6 correct? 7 A Correct. 8 Q And here we have Dr. Cramer saying in 9 2007 there is no proof that talc used externally 10 reaches the pelvis, correct? 11 MS. PARFITT: Objection. Form, 12 misstates the article. 13 BY MR. KLATT: 14 Q Is that what he said? 15 A That's what it says. 16 Q And you -- 17 MS. PARFITT: Wait. Wait. Wait. Wait, 18 you let him finish. He said, That's what he said 19 -- finish, please. Thank you, Michael. 20 THE WITNESS: The -- the word "proof" in 21 that sentence is a red flag. I'm not sure what 22 they mean -- they meant by proof. They might 23 have -- well have said, There is evidence that, 24 but it is not yet conclusive. That is one 25 interpretation of a sentence like, There is no</p>	<p>1 MS. PARFITT: Yeah. 2 THE WITNESS: You have very good eyes if 3 you saw me looking at the Heller. I actually 4 wasn't, but -- 5 BY MR. KLATT: 6 Q I thought you were on that page. 7 A Well, I was -- I scanned each of the 8 four pages. There aren't that many pages. The -- 9 I see mention of the Heller article. 10 Q On page 500? 11 A Yes, I do see that. 12 Q Do you see where Dr. Cramer in 2007 is 13 suggesting that the explanation for the Heller 14 study may be contamination that was introduced 15 during the processing of the tissue specimens? 16 A So I see that he says it might have been 17 introduced during processing, and it's a potential 18 weakness. He doesn't affirm that it is. He says 19 it might be. 20 Q So contamination is another explanation 21 potentially for why you might find talc in ovarian 22 or gynecologic tissues? 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I -- I guess so. Not 25 being an expert in pathology and physiology, I --</p>

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<p>1 that seems like a plausible -- seems to me like a</p> <p>2 plausible alternative explanation.</p> <p>3 BY MR. KLATT:</p> <p>4 Q You go on and comment in the next</p> <p>5 paragraph of your biologic plausibility on two</p> <p>6 trace heavy metals, chromium and nickel compounds,</p> <p>7 correct?</p> <p>8 A So where are we -- oh, yeah. Yes.</p> <p>9 Q You're aware that IARC has made</p> <p>10 determinations regarding chromium and nickel</p> <p>11 compounds, correct?</p> <p>12 A Yes, correct.</p> <p>13 Q And neither one of the determinations</p> <p>14 found they were linked to ovarian cancer at all,</p> <p>15 correct?</p> <p>16 A That's correct.</p> <p>17 Q They found they were related to nasal,</p> <p>18 sinus and lung cancers in people, primarily</p> <p>19 workers, who had breathed the fumes, correct?</p> <p>20 A That's correct.</p> <p>21 Q So that's no way analogous to any trace</p> <p>22 heavy metals in talc, correct?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 THE WITNESS: It's -- it's not directly</p> <p>25 relevant. It may be indirectly relevant. The</p>	<p>1 THE VIDEOGRAPHER: This ends -- this</p> <p>2 ends the deposition of Jack Siemiatycki.</p> <p>3 We are going off the record at 9:28 p.m.</p> <p>4 (Whereupon, the deposition</p> <p>5 of JACK SIEMIATYCKI, Ph.D. was</p> <p>6 concluded at 9:28 p.m.)</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 evidence that allowed IARC to make determinations</p> <p>2 about lung cancer risks is evidence from</p> <p>3 industrial cohorts of males.</p> <p>4 And so there has never been an</p> <p>5 evaluation of ovarian cancer risks in relation to</p> <p>6 exposed women to chromium and nickel. It's terra</p> <p>7 incognita basically.</p> <p>8 BY MR. KLATT:</p> <p>9 Q And so following up on that, you're not</p> <p>10 aware of any evidence at all that women who have</p> <p>11 used externally applied talcum powder to the</p> <p>12 genital area have higher blood or tissue levels of</p> <p>13 chromium or nickel compounds than women who've</p> <p>14 never ever used talc at all, correct?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: I've -- I'm not aware of</p> <p>17 any evidence.</p> <p>18 MR. KLATT: I think that's all the</p> <p>19 questions I have.</p> <p>20 MS. PARFITT: I have no further</p> <p>21 questions.</p> <p>22 Dr. Siemiatycki, you are done. We will</p> <p>23 read and sign.</p> <p>24 Thank you, Leslie.</p> <p>25 Thank you all.</p>	<p>1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER</p> <p>2 The undersigned Certified Shorthand Reporter</p> <p>3 does hereby certify:</p> <p>4 That the foregoing proceeding was taken before</p> <p>5 me at the time and place therein set forth, at</p> <p>6 which time the witness was duly sworn; That the</p> <p>7 testimony of the witness and all objections made</p> <p>8 at the time of the examination were recorded</p> <p>9 stenographically by me and were thereafter</p> <p>10 transcribed, said transcript being a true and</p> <p>11 correct copy of my shorthand notes thereof; That</p> <p>12 the dismantling of the original transcript will</p> <p>13 void the reporter's certificate.</p> <p>14 In witness thereof, I have subscribed my name</p> <p>15 this date: February 4, 2019.</p> <p>16</p> <p>17</p> <p>18 _____</p> <p>19 LESLIE A. TODD, CSR, RPR</p> <p>20 Certificate No. 5129</p> <p>21 (The foregoing certification of</p> <p>22 this transcript does not apply to any</p> <p>23 reproduction of the same by any means,</p> <p>24 unless under the direct control and/or</p> <p>25 supervision of the certifying reporter.)</p>

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<p>1 INSTRUCTIONS TO WITNESS</p> <p>2 Please read your deposition over carefully and</p> <p>3 make any necessary corrections. You should state</p> <p>4 the reason in the appropriate space on the errata</p> <p>5 sheet for any corrections that are made.</p> <p>6 After doing so, please sign the errata sheet</p> <p>7 and date it.</p> <p>8 You are signing same subject to the changes</p> <p>9 you have noted on the errata sheet, which will be</p> <p>10 attached to your deposition. It is imperative</p> <p>11 that you return the original errata sheet to the</p> <p>12 deposing attorney within thirty (30) days of</p> <p>13 receipt of the deposition transcript by you. If</p> <p>14 you fail to do so, the deposition transcript may</p> <p>15 be deemed to be accurate and may be used in court.</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2 I, _____, do hereby</p> <p>3 certify that I have read the foregoing pages, and</p> <p>4 that the same is a correct transcription of the</p> <p>5 answers given by me to the questions therein</p> <p>6 propounded, except for the corrections or changes</p> <p>7 in form or substance, if any, noted in the</p> <p>8 attached Errata Sheet.</p> <p>9</p> <p>10 _____</p> <p>11 JACK SIEMIATYCKI, Ph.D. DATE</p> <p>12</p> <p>13</p> <p>14 Subscribed and sworn to</p> <p>15 before me this</p> <p>16 _____ day of _____, 20____.</p> <p>17 My commission expires: _____</p> <p>18 _____</p> <p>19 Notary Public</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p>Page 355</p> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p> <p>25</p>	

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